



Spectrum
Health

GREAT MOMs Program

For Women During Pregnancy

A MOUD (Medication for Opioid Use Disorder)
Obstetrician/Certified Nurse Midwife (CNM)
and Medical Assistant Model of Office-Based
Opioid Treatment

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Thank You

We would like to acknowledge Boston Medical Center's OBOT program for allowing us to use their model as the template for expanding to women's health and in areas where nurse care management is less accessible.

Purpose

The purpose of this clinical guideline is to provide detailed policies and protocols of the office-based opioid treatment program for pregnant woman with use of buprenorphine in the treatment of opioid use disorders in combination with prenatal care at Spectrum Health's GREAT MOMs Program.

These policies and protocols are meant to provide best practice guidelines to clinicians utilizing buprenorphine management of opioid use disorders in pregnant women, and to expand access to treatment.

Philosophy

A substance use disorder is a chronic medical condition that responds best when treated with evidence-based, patient-centered, comprehensive medical care. Patients engaged in OBOT deserve to be treated with dignity and respect. The goal of OBOT is a cessation or reduction in harmful substance use, active participation and engagement in treatment, restoration of normal physiologic functions and an improvement in one's quality of life.

Introduction

SUD is a growing problem among pregnant women in the state of Michigan. According to the Michigan Prescription Drug and Opioid Abuse Task Force *Report of Findings and Recommendations for Action*:

- Heroin use among women has increased 100% in the past 10 years.
- Increase in heroin use has led to a significant increase in the number of children being born with neo-natal abstinence syndrome (NAS).
- In 2012, 21,732 babies born in the United States suffered from NAS. This is a five-fold increase from 2000.
- The average hospital costs for an infant born with NAS is \$66,700 compared to \$3,500 for an infant born without NAS.

Women with SUD seeking prenatal care often have complex medical and psychiatric problems. SUD is also associated with poor perinatal outcomes. The timeliness of prenatal care and care during and after labor and delivery is important for both the safety and well-being of the mother and her infant. Specifically, untreated perinatal opioid addiction is associated with low birth weight, still birth, placental abruption and prematurity.¹ In addition, profound impacts on the neonate, both immediate and long-term, are possible if addiction remains untreated. Women who enter treatment for their opioid use disorder during pregnancy tend to have higher rates of compliance with prenatal care and have neonates with less pharmacologic intervention in the immediate postpartum period.² This decreases financial cost to health care systems, eases the emotional burden to the mother and family, and ultimately alleviates community burden.

The World Health Organization recommends comprehensive programs that address SUD in the prenatal care setting. They call for "a range of gender-sensitive prevention and treatment interventions that can respond to multiple needs, including childcare needs, comorbid mental and concurrent medical conditions, blood-borne viruses and other infectious diseases, poor diet and psychosocial problems, homelessness, poverty and violence."³ The CDC recommends sensitivity to the treatment of women with opioid use disorder that includes care that is comprehensive, gender-responsive, trauma-informed and family-centered.

Due to the unique needs of women and families who are facing SUD during pregnancy, childbirth, and beyond in Kent County, Michigan, the Division of Maternal Fetal Medicine at Spectrum Health (SH) created a comprehensive prenatal care program, *Grand Rapids Encompassing Addiction Treatment with Maternal Obstetric Management (GREAT MOMs)*.

1. *The ASAM: National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*. (2015). Chevy Chase, MD: American Society of Addiction Medicine.

2. Goler, N.C, Armstrong, M.A., Taillac, C.J., & Osejo, V.M. (2008). Substance abuse treatment linked with prenatal visits improves perinatal outcomes: a new standard. *Journal of Perinatology*, 28(9), 597-603. doi:10.1038/jp.2008.70.

3. Goodman, D. (2015). Improving Access to Maternity Care for Women with Opioid Use Disorders: Colocation of Midwifery Services at an Addiction Treatment Program. *Journal of Midwifery and Women's Health*, 60(6), 706-712. doi: 10.1111/jmwh. 12340.

Pilot Program

Since the initial pilot implementation period of the GREAT MOMs program through February 2020, 66 patients have enrolled in the program and 42 babies were born; the average gestational age at birth is 37.23 weeks. The data included two sets of twins, which were born at 26 weeks and 34 weeks. Both sets of twins were delivered early due to intrauterine growth restriction, not related to the treatment for opioid use disorder. The average length of hospital stay for babies after birth is 13.28 days. If the two sets of twins are removed from the data, due to the fact that they had to stay in the hospital for developmental concerns unrelated to the opioid use disorder. The number decreases to 9.9 days in the hospital. Our organization has a policy that the babies born on buprenorphine must stay for a minimum of five days for observation. A total of 33 patients made it to their six-week postpartum appointment, which is 78 percent of patients.

With the initial success of the GREAT MOMs comprehensive prenatal care program, we see an opportunity for improvement and expansion.

Staff Requirements

The GREAT MOMs program is led and maintained by the Spectrum Health addiction team and does include:

1. An addiction prescriber embedded in a woman's prenatal care clinic.
 - Appropriate licensure of physicians and advance practice professionals such as: Nurse practitioners, physician assistants and certified nurse midwives (CNMs).
 - A comprehensive program that supports transitioning pregnant patients to postpartum treatment.
 - The coordination with appropriate specialties caring for women and their neonates at all points during their childbearing year and beyond: Maternal-Fetal Medicine (MFM), Obstetrics, Midwifery, Addiction Medicine, Family Medicine and Pediatrics/Neonatology.
2. Midwifery-led prenatal care in collaboration with MFM. The core of the midwifery model of care is family-centered, patient-empowered care. Certified nurse midwives (CNM) are ideal providers of compassionate, coordinated, cost-effective care for this population. The CNMs may also act in an educator role during labor and delivery, ensuring that residents and staff are aware of pain management plans, encouragement of bonding, breastfeeding, mother-infant dyad nonseparation and communication with the neonatal team, including NICU.
3. A certified medical assistant to support providers.
4. Program manager to ensure appropriate outcomes and to oversee the program.
5. Registered nurses to coordinate calls when clinic is not open.

Partnering with Community

Partnering with community mental health agencies, such as the health department to provide resources for mental health services, counseling and the psychosocial needs of the patients.

Partnering with outpatient clinics such as specialty addiction clinics and family medicine clinics with the capability of providing follow-up postpartum care, addiction care and pediatric/well-child visits.

MOUD Provider Requirements

Buprenorphine, Buprenorphine/Naloxone

Qualifications: Qualified providers must obtain a waiver of authority to prescribe any medication that is schedule III, IV, or V and FDA approved for the treatment of opioid use disorder for the purpose of detoxification or maintenance treatment of patients with opioid use disorder. With DATA 2000, physicians became legally qualified to receive waiver training. In 2016, the Comprehensive Addiction and Recovery Act was signed into law, increasing buprenorphine prescription authority to also include physician assistants and nurse practitioners. In 2018, the SUPPORT ACT expanded to include all advanced practice nurses, including certified nurse midwifery.

Physician Waiver Eligibility: To be eligible for a waiver, physicians must have a current state medical license, a valid registration number from the US Drug Enforcement Agency (DEA), completion of an eight-hour approved waiver training course and one or more of the following:

- Board subspecialty certification for addiction psychiatry (American Board of Medical Specialties), addiction medicine (American Society of Addiction Medicine), (American Osteopathic Academy of Addiction Medicine or American Board of Medical Specialties).
- OR-
- Participation as an investigator in one or more trials that led to the FDA approval of buprenorphine/naloxone or another schedule III-V narcotic medication used for the maintenance or detoxification treatment of opioid addiction.
- OR-
- Other training or experience deemed equivalent by either the State Medical Board or by the Secretary of Health and Human Services (HHS).

PA & Advanced Practice Nursing Eligibility: To be eligible for a waiver, these providers must complete 24 hours of approved training that covers the following topics: opioid maintenance and detoxification, clinical use of all FDA-approved drugs for MOUD, patient assessment, treatment planning, psychosocial services, staff roles and diversion control. Those providers, who are approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician if required by law in their state.

Referrals: Providers must be able to refer patients to counseling and psychiatric services.

Patient Limits: For the first year following receipt of a waiver, providers are limited to treating 30 active patients at any given time; after the first year, they are limited to treating 100 patients at any given time (e.g., prescription written for 28 days, patient is discharged, that patient continues to count under that physician number until the end of that 28-day prescription). For a provider to become eligible to treat up to 100 patients, they need to apply to SAMHSA's Center for Substance Abuse Treatment (CSAT) at www.buprenorphine.samsha.gov for the extended waiver.

There are expanded limits to treat up to 275 patients. Eligible prescribers must complete a 'Request for Patient Increase Form' and receive approval prior to increase. To be eligible for a patient limit of 275, a prescriber must have a current waiver to treat up to 100 patients and must have maintained that waiver for at least one year without interruption.

Prescribers wishing to increase to a patient limit of 275 must also meet one of the following requirements:

- Physician who holds a board certification in addiction psychiatry or addiction medicine

Certifying agencies: American Board of Medical Specialties (ABMS), American Society of Addiction Medicine (ASAM), American Board of Addiction Medicine (ABAM), American Osteopathic Academy of Addiction Medicine (AOAAM)

-OR-

- Prescribers who practice in a "qualified practice setting".

A "qualified practice setting" must provide professional coverage for patient emergencies during hours when the practice is closed, provide access to case management services, accept third-party payment for health service costs, utilize health information technology and be registered by their state prescription drug monitoring program where operational.

CNM Requirements

Certified nurse-midwives are registered nurses who have graduated from a nurse-midwifery education program accredited by the Accreditation Commission for Midwifery Education (ACME) and have passed a national certification examination to receive the professional designation of certified nurse-midwife.

www.midwife.org

Registered/Certified Medical Assistant Requirements

A medical assistant is a person who graduated from either an accredited medical assisting program or a medical assistant program that is housed within an accredited institution. To become registered or certified one must comply with the eligibility requirements of American Medical Technologist (RMA) or American Association of Medical Assistants (CMA).

Program Manager

The Program Manager is responsible for managing the operations of the program. Works within the budget, to advertise, train and oversee staff. Ensuring the safety and overall experience for the patient is exceptional. The person in this role should ideally have clinical knowledge as well as administrative acumen.

Program Requirements

SAMHSAs Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapies

Buprenorphine Administrative Requirements

- Certification, accreditation and waiver approval.
- Maintain accurate provider records.
- Records on dispensation of buprenorphine and buprenorphine/naloxone must be kept in accordance with DEA regulations for controlled substances as described in 21 CFR 1304.03(b).
- Records on prescription and dispensation of medications for the detoxification and maintenance treatment of opioid use disorder must be kept in accordance with DEA regulations 21 CFR 1304.03(c)
 - Maintain log to include patient identifier, name, dose and quantity of drug prescribed/dispensed and date.
 - Requirement may be fulfilled by keeping copies of prescriptions in the patient record. Electronic medical records where the prescription records can be accessed fulfills this requirement and there is no need to keep copies of the prescriptions in your office.
 - For DATA 2000 compliance, the DEA only needs to review records for medications used in the treatment of opioid use disorder; therefore, an option is to keep separate records for these medications to facilitate the review.

Candidates for GREAT MOMs Program

- Patient must have a *DSM-5* diagnosis of Opioid Use Disorder.
- Patient must be pregnant.
- Patient must agree with the goals of GREAT MOMs program:
 - Prevention/reduction of withdrawal symptoms and cravings for opioids.
 - Addressing any psychiatric problems through consultation with community resources, follow through with necessary referrals and treatment.
 - Restoration of normal physiological functions that may have been disrupted by substance use and improvement in quality of life.
- Patient is able to come to visits during office hours of operation.
- For patients seeking treatment with agonist medications: they must not have chronic pain requiring ongoing opioid management beyond buprenorphine/naloxone.
- Patient must be able to be treated in an office-based setting safely without harm to self or others.
- Patient should be willing to address use of other harmful and/or illicit substances.
- Treatment team should carefully assess patient for appropriateness of medication treatment in an office-based setting.

Patient Initiation Roadmap

- GREAT MOMs referral process.
- Initial screening by referring provider.
- OBOT provider visit.
- Certified nursing midwife intake.
- Consents.
- Stabilization.
- Maintenance.

Referral Process to GREAT MOMs

If the patient is currently on buprenorphine from a prescriber with verified pregnancy and willing to engage in the GREAT MOMs program, the provider can place referral to GREAT MOMs program noting date that most recent MOUD prescription expires, so patient does not run out of medication prior to an intake. Prescriber must be able to take the patient back after pregnancy.

Obstetrics (OB) offices can refer patients that screen positive for an opioid use disorder to the program and after pregnancy GREAT MOMs will work to find a provider to follow the patient. Patients are started on medication within 72 hours of trying to access care.

Referring provider screen includes: Review of medical, social and substance use history, as well as, current use. Determine the patient's demographics, living situation, as well as safety and treatment goals. Try to determine the expected due date (EDD) or verifying active pregnancy using a point of care test.

OBOT Intake

OBOT program manager and nurses performs an initial screening to make a decision about potential appropriateness of patient receiving medication for substance use disorder in an office-based setting. Appropriate candidates proceed directly into GREAT MOMs.

Intake performed by MOUD prescriber/certified nurse midwife.

MOUD Prescriber Intake

The MOUD prescriber intake includes:

- Information to lay the groundwork for a therapeutic relationship with the patient. Assess patient goals for treatment, strengths for obtaining recovery and risks to treatment success.
 - The MOUD prescriber values the uniqueness of each individual and helps each person define their own goals.
- Assessment of substance use including substance use history, current status, prior treatment, goals during pregnancy and beyond.
- Review of medical, mental health and social history. Obtain appropriate signed consent forms to assist with collaboration of care with outside providers and supports.
- Education on medication for addiction treatment: What it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, induction and maintenance processes. This includes discussing potential effects on the fetus, neonatal abstinence syndrome and analgesics during labor and delivery as well as the potential involvement of Child Protective Services (CPS).
 - The MOUD prescriber reinforces that an opioid use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBOT team will support the patient throughout the recovery process, even in the event of a return to drug use. The patient's treatment plan will be augmented as necessary to assist the patient in achieving recovery and meeting their identified treatment goals.
- Harm reduction education: Overdose prevention education, overdose reversal with naloxone, rescue breathing, ensuring patient has access to naloxone (including via co-prescribing).
- Obtain laboratory tests as clinically needed.
 - Consider: Complete blood count, comprehensive metabolic panel, hepatic function, pregnancy test, RPR, hepatitis A, B and C serologies, HIV.
- Review of treatment agreement and program expectations. Patient signs treatment agreement and consents for treatment.

- Program expectations include:
 - Appointment frequency with MOUD Prescriber and Certified Nurse Midwife.
 - Counseling and psychiatric assessment and follow-up if warranted.
 - Medication refills.
 - Patient-centered treatment planning and review.
 - Introduction to members of treatment team.
 - Review the medication safety and discuss responsibilities for safe medication storage.
 - Review clinic hours and times available for scheduling visits, including after-hours emergency contact information.
 - If unable to meet the patient's needs and the program requirements, site will refer the patient to another treatment setting that may be better able to meet the needs of the patient.

Certified Nursing Midwife/OB Provider Intake

- Complete history and physical as indicated.
- Try to determine patient's estimated due date.
- Perform risk screening for tuberculosis (TB).
- Schedule dating ultrasound upon entry to care if not done.
- Check patient's record in the Prescription Drug Monitoring Program (PDMP).
- Discuss tobacco use.
- Mandatory screening at time of intake includes:
 - Toxicology screening.
 - Prenatal labs.
 - HIV testing.
 - Ensure PPD screen is up to date per institution's protocol.
- Obtain laboratory tests as clinically needed.
 - Consider: Complete blood count, comprehensive metabolic panel, hepatic function, RPR, hepatitis A, B and C serologies.

Consents

In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2).

Additionally, the law requires written patient consent before information about addiction treatment can be disclosed to any other source. For OBOT, this may include any communications with other providers, treatment centers, significant others or pharmacies.

Specifications that are Prohibited (without Consent)

- Providing information regarding a patient's past, present or future participation in addiction treatment.
- Disclosing or transmitting a patient's addiction-related medical records.
- Use of a letterhead that identifies the office as an addiction treatment provider.
- Providing information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment.
- Providing information about deceased patients.
- Verifying information that inquirers already possess — in other words, a program can neither confirm nor deny that a patient was being treated there. (SAMHSA, 1994b).
- There are some exceptions to the disclosure laws, such as in the case of medical emergencies or specific legal circumstances. Other than in the case of a medical emergency, check with your organization's legal counsel prior to making disclosures without consent.

Visit with OBOT Provider/Certified Nursing Mid-Wife

- OBOT provider will assess patient at every visit to ensure patient is appropriate for medication for addiction treatment with buprenorphine/naloxone.
- Patient will follow up with OBOT provider every one to two weeks, up to four weeks as appropriate.
- Follow up with OB provider as recommended by ACOG guideline, more often if needed.
- Follow up with primary care provider as warranted based on medical needs.

Treatment Initiation, Stabilization & Maintenance

Checklist: Prior to Treatment with Buprenorphine/Naloxone

- Treatment agreement and consents are reviewed and signed.
- Reinforce to patient the need for frequent appointment adherence and establish whether this is realistic. If patient states it is not manageable, this needs to be addressed with the team prior to treatment.
- The patient should be encouraged to have counseling in place or be working towards establishing treatment with a counselor. Counseling may be group-based or individual.
- Toxicology screen completed and reviewed by OBOT team at most visits.
- If patient is not currently on MOUD, then the MOUD prescriber will determine if patient is buprenorphine/naloxone naive.
- If patient is pregnant and on methadone, patient cannot be switched to buprenorphine/naloxone during pregnancy. This is due to possible risks associated with severe withdrawal during pregnancy including, pre-term labor.

Buprenorphine/Naloxone Stabilization

Goal: Stabilization of dosing. Target buprenorphine/naloxone dose equals 8 - 16mg/day (maximum of 24mg/day) or less. Medication may be taken in divided doses, up to twice daily.

- Opioid blockade is typically reached at 16mg and is recommended in the early stages of recovery. <http://www.naabt.org>
- Divided dosing is especially helpful for patients with chronic pain for dual effectiveness and avoidance of other opioid medications. For pain, may divide up to every 10 hours.
- This medication has a long half-life. The majority of patients take buprenorphine/naloxone twice daily; the prescription may need to be specifically written as twice daily dosing to allow some patients to receive it twice daily while engaged in treatment for substance use disorder or in a medical setting.
- Patient returns to clinic after one week for assessment, prescription renewal, urine toxicology screening, counseling, education, support and evaluation of mental health and other needs.
- No prescriptions lasting longer than one week are to be given during this phase.
- Patient sees MOUD Provider/CNM weekly for four to six weeks until stable. If toxicology screens are as expected and the patient is adherent to the treatment plan, they may then progress to the maintenance phase.

Pregnancy and Breastfeeding

Active opioid use disorder in pregnancy is considered high-risk.

- First trimester: Risk for spontaneous abortion.
- Third trimester: Risk for withdrawal-induced fetal distress, premature labor and intrauterine death.
- Educate pregnant patients on the benefits of maintaining opioid replacement during pregnancy.
 - Decreased risk for relapse and therefore reduced complications from illicit opioid use.
 - Constant levels of fetal opioid exposure result in reduced risk for adverse fetal outcomes related to multiple withdrawals.
 - Decreased rate of adverse fetal outcomes such as low birth weight.
 - Incidence of neonatal abstinence syndrome is 47%.
- Both methadone and buprenorphine (both combo and mono-tablet formulations) are Category C in pregnancy.
- There is more substantial data and clinical experience utilizing methadone in pregnancy.
- In 2012, the American College of Obstetricians and Gynecologists (ACOG) concluded that there is evidence to support the use of buprenorphine as a potential first-line medication for women with an opioid use disorder.
- A longitudinal study of 73 children evaluated at 24 months (n = 24 exposed to buprenorphine in utero, and n = 19 exposed to methadone in utero, n = 30 non-exposed controls) found no differences between groups in temperament or neurological development during the first two years of life.¹

- A double-blind randomized controlled trial of 175 pregnant women with opioid use disorder treated with buprenorphine or methadone maintenance compared maternal and neonatal outcomes between the two groups. A total of 131 neonates were born to mothers followed through the end of their pregnancy (58 exposed to buprenorphine and 73 exposed to methadone).²
 - Neonates in the buprenorphine group required significantly less morphine (mean dose, 1.1mg vs. 10.4mg) than neonates in the methadone group. They also had significantly shorter hospital stays (10.0 days vs. 17.5 days) and significantly shorter duration of treatment for neonatal abstinence syndrome (4.1 days vs. 9.9 days). The two groups did not vary with regard to maternal or neonatal adverse events.

Buprenorphine in Pregnancy

- Additional research is still needed; a recent review comprised of preliminary findings from seven previously published studies found no evidence of adverse maternal or neonatal outcomes related to the use of buprenorphine/naloxone as compared to buprenorphine alone (mono product) or methadone.³ Currently many providers use buprenorphine/naloxone for treatment of opioid use disorder during pregnancy without complications or notable adverse events.

Breastfeeding Protocol

- Women should be encouraged to breastfeed provided their UTS are negative for non-prescribed opioids and the mother is not prescribed any other medications that are contraindicated for breastfeeding for a minimum of 30 days prior to delivery. She should also be abstaining from use of other illicit substances, including marijuana.
- Breastfeeding women should be maintained on buprenorphine/naloxone.
- Buprenorphine/naloxone is passed into breast milk at 1:1 plasma: milk ratio.
 - Because of poor oral bioavailability of buprenorphine/naloxone, the breastfeeding infant is exposed to only 1/10 of buprenorphine/naloxone ingested.
 - Breastfeeding during buprenorphine/naloxone use does not suppress neonatal abstinence syndrome (NAS). However, the close contact afforded by breastfeeding has been shown to assist with symptoms of NAS and enhances maternal-child bonding.
 - Cessation of breastfeeding is not associated with the onset of neonatal abstinence syndrome.

Ongoing Patient Management: OBOT Agreement & Clinic Policies

Treatment Agreement

Goal: Engage patients in the treatment plan, along with the OBOT team. Individualize treatment to meet the needs of the patient. Encourage patient involvement in their treatment.

- See treatment agreement forms.
- Set clear expectations/guidelines.
- Explain treatment agreement verbally and provide in written form, which patients will sign and date. This form will be kept in the patient record. Review each line of the contract and give a copy to the patient to take home for their review.
 - Encourage patients to ask questions.
 - Review this agreement again with the patient intermittently during the course of treatment and as needed.
 - Provide reassurance about common issues, such as patients' concerns about entering treatment (provide education around options and support), or the risks of transferring care from one form of medication treatment to another, or patients' ambivalence about such changes.
- The agreement reinforces that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBOT team will support the patient throughout the recovery process, even in the event of a return to use. The patient's treatment plan will be augmented as necessary to assist the patient in achieving identified treatment goals.
- The patient can expect:
 - To be treated with dignity and respect.
 - To be notified if the office is closed and how to seek assistance if needed.
 - That confidentiality will be maintained in compliance with CFR 42.
 - To have a means for contacting a member of the OBOT team or a colleague for emergencies at night, on weekends and when the office is closed.

Adherence to Program Policies and Treatment Protocols:

- *Clinical Appointment Policy:* All patients who participate in the Office Based Opioid Treatment program are required to keep all appointments with their MOUD providers and Certified Nurse Midwife. These appointments are critical to the continuation of care.
- If an appointment cannot be kept, it is the patient's responsibility to reschedule the appointment.
- Patients are expected to make an effort to arrive on time for scheduled appointments.

- If patients do not show up for medical appointments and do not call to inform OBOT staff that they are unable to make the appointment, or arrange for rescheduling, the treatment plan will be revised accordingly.
 - Consider increasing visit and prescription frequency until the patient is seen by their provider.
- Patients struggling to meet program requirements may need to be referred to another program or level of care.
- Procedures for contacting the OBOT team when the office is closed:
 - All patients can call the office number to be connected with an after-hour's provider. They will reach a nurse and the nurse will reach out to the provider and call the patient back. This number should be called off hours if the patient has a medical emergency that may require pain management, or if they have an issue with their prescription.

Behavior Expectations

To provide an optimum treatment environment for all, patients, visitors and staff are expected to maintain appropriate behaviors in the clinic and on the clinic grounds.

Urine Drug Screening Policy

- All belongings (coats, bags, etc.) are left in the presence of the medical assistant or outside the bathroom door.
- Patient will be required to wash hands in front of medical assistant prior to providing a urine specimen.
- Medical assistant will provide patient with an empty labeled urine cup to collect specimen.
- Once patient provides urine specimen to gloved medical assistant the patient then can flush the toilet and wash their hands.
- Urine samples will be required at each visit.
- Clinic policy: Any questionable urine is automatically repeated the same day.
- On rare occasions, providers may request an observed urine specimen.
- Medical assistants will follow standard work procedure for all urines collected.

Tampering

If the urine sample is questionable:

- The patient will be asked to repeat urine screen immediately; a discussion will take place to address what may be going on in an effort to assist the patient.
- The patient will be counseled by the MOUD Provider about the importance of UDS monitoring and honesty in treatment to ensure that the team has the ability to provide appropriate treatment. Reinforce that the OBOT team is here to help if the patient is struggling.
- The patient is reminded that tampering with a urine sample may lead to a referral to a higher level of care.
- When an appropriate urine sample is obtained, the patient will receive a buprenorphine/naloxone prescription refill. If needed, the patient will receive a daily script for up to one week to obtain an appropriate urine sample. If the patient is unable to provide one in that allotted time, this may be an indication that they need a higher level of care.

Buprenorphine/Naloxone Prescription Policies

The role of the MOUD provider/certified nurse midwife, the office staff and the patient in the handling of prescriptions/medications:

- Prescriptions will be processed by an MOUD provider who will review the medication record, consult with CNM, pharmacy and the Prescription Drug Monitoring Program (PDMP) if needed, to confirm dosage, refill amounts and timing of refill.
- Medical assistant will check insurance coverage, preferred covered medication formulary and need for prior authorization. There is no prior authorization for persons with Medicaid in Michigan.
- Following confirmation, MOUD provider/CNM/nursing will generate an electronic prescription under the waived provider's name. If not signed directly by the MOUD provider, forward request to provider for co-signature as appropriate.
- Prescription records are maintained in the electronic medical record for review by clinicians as needed and for DEA regulatory purposes.

Maximum Number of Days Medication Will Be Provided with a Prescription

- At the time of treatment initiation, all prescriptions will be written for a maximum of one week with no refills.
- Following four to six weeks of treatment, if the patient is moving into the stabilization phase, prescription refills will increase to two-week intervals with up to one refill.
- If patient is less than 28 weeks pregnant and enters GREAT MOMs already in the maintenance phase and receiving monthly prescriptions, with team approval, monthly scripts can continue until 28 weeks in accordance with current ACOG recommendations for prenatal care. Prescriptions are sent to the designated pharmacy within 24 hours of a scheduled visit.
- Patients must keep scheduled appointments to obtain prescription refills.

- If a patient is not appropriate for longer interval prescriptions, the OBOT team will make the decision to continue with shorter-interval prescriptions.
- If a patient is homeless, or is living in an unsafe or unstable setting, the OBOT team, along with the patient, will develop a plan that promotes the security of their treatment. This may affect the duration of prescriptions.

Lost, Stolen or Destroyed Buprenorphine/Naloxone

- *Lost or Stolen Medication:* Buprenorphine/naloxone prescriptions if lost or stolen will be reviewed on an individual basis by the OBOT team to determine the best possible solution. If a decision is made to replace the medication, it will be an out of pocket expense for the patient, insurance will not cover the medication early. If more than a one-week supply of replacement prescription is needed, the prescription amount will return to weekly prescriptions for four to six weeks following the stabilization phase of treatment.
- *Destroyed/Damaged:* If able, the patient should be instructed to bring the reported medication in for the OBOT team to review. A decision will be rendered by the team on how best to proceed. If a patient reports destroyed/damaged medication, the prescription amount will go back to weekly prescriptions for 4-6 weeks following the stabilization phase of treatment.
- In the event of, lost, stolen, destroyed or damaged medications, prior to receiving a replacement prescription, the patient may be asked to return to the OBOT clinic within 24 hours for assessment and toxicology screen. At this time, patients will receive additional education about safe handling and storage of buprenorphine/naloxone by the OBOT team to prevent these events from reoccurring. The treatment plan should be reviewed along with length of prescription and frequency of visits to further assess and ensure that there are not additional concerns or needs.
- If the patient continues to experience events of lost, stolen, damaged or destroyed medications, the team will meet to address this and the potential need to refer the patient to a more structured treatment setting to better safeguard their treatment and their recovery.

Safe and Proper Storage of Medication⁴

- Keep medication out of sight/reach of children.
- Use a locked box, bag or cabinet for safe storage.
- Do not put tablets/films in purse, on counters, sinks, dresser and nightstands or in any public unsecure space.
- It is easier for children to put small pieces and crumbs in their mouth.
- For tablets to prevent breakage, keep cotton or tissue in the bottle.
- Always keep in a labeled prescription bottle with child-proof cap.
- Patient's prescribed buprenorphine/naloxone film should be stored with an official pharmacy label at all times. Patients may request a second label from the pharmacy if they plan to carry a limited amount of medication on their person. This is not recommended.
- Avoid carrying medication in your pocket, bag, purse or backpack.
- Avoid leaving in the bathroom, car or any public space.

- **Call 911** if an accidental exposure occurs and/or go to the nearest emergency department.
- Suggest to patients that they obtain a locked bag or a lock box to store buprenorphine/naloxone and any other controlled substances safely and out of reach.
- Reinforce safe storage out of common areas and away from children and others.

4. Adapted from "Protecting Others and Protecting Treatment" STATE OBOT (State Technical Assistance Treatment Expansion Office Based Opioid Treatment of Buprenorphine), and Massachusetts Department of Public Health Bureau of Substance Abuse Services (BSAS). 2016.

Birth Plan/Pain Management During Labor or C-Section

Birth Plan

General Overview:

This woman is on medication for addiction treatment for an opioid use disorder. There are some unique and important considerations for her care during labor and delivery and in the immediate postpartum period.

- The partial blockade by buprenorphine can increase the dose of pain medication needed for effective analgesia.
- Maintenance medication, in this case buprenorphine, does not treat pain. Hyperalgesia, a worsening of pain perception due to opioids, is associated with their use. Continuation of their maintenance medication is imperative.
- Nalbuphine and butorphanol are contraindicated for patients on buprenorphine as they can precipitate withdrawal. If they are inadvertently given, fentanyl IVP should be administered until withdrawal symptoms abate.
- IV access may be difficult, consider consult to IV access team and, if needed, PICC or central line. In general, we recommend avoiding central line placement in laboring women if at all possible.
- Please contact the GREAT MOMs program to notify of admission during clinic hours.
- Review newborn testing recommendations with patients privately.

Plan SVD:

- Continue buprenorphine at prescribed doses (this information can be found in the outpatient record or by accessing the PDMP). NOTE: While the patient is admitted to the hospital, a provider may legally order buprenorphine to maintain a patient's outpatient dose during her hospitalization. Documentation of this Federal regulation is available at: <https://www.deadiversion.usdoj.gov/>
- An epidural with low dose, local anesthetic + fentanyl in standard dosing is recommended in labor this should be offered as early as possible.
- May give NSAIDs (i.e., Motrin 800mg Q8hrs ATC) post vaginal delivery. Recommend giving in scheduled dosing, NOT PRN.
- If with a significant tear or other significant pain, consider opioid analgesia at 1.5 to 2x increased opioid dose and more frequent intervals than non-opioid tolerant patients.
- Avoid discharging patient with a prescription for oral opioid pain medication.

Back-up C-Section:

- Continue buprenorphine at prescribed doses (this information can be found in the EPIC outpatient record or by accessing the PDMP).
- We recommend either spinal or epidural dura-morph unless there is a patient-specific contraindication
- Scheduled 30mg IV ketorolac every six hours until scheduled PO ibuprofen can be started +/- prn dilaudid if needed for breakthrough.
- PCA dilaudid will most likely be needed if the patient does not receive neuraxial dura-morph. TAP blocks can also be considered in these cases if the patient has not already received a prohibitively large dose of local anesthetic through an epidural catheter.
- Transition to oral pain medication as soon as possible. Anticipate scheduled dosing of 1.5 to 2x increased opioid dose and more frequent intervals than used in non-opioid tolerant patients.
- Do not write for more than #20 doses of oral opioid pain medication and verify that patient knows to call the GREAT MOMs program for post-partum pain management.

General Discharge Instructions:

- Patient should have an appointment with the GREAT MOMs program made for two weeks postpartum for addiction follow up as well as postpartum follow-up evaluation with CNM.
- Please remind the patient that it is her responsibility to contact GREAT MOMs for a refill during regular clinic hours if needed on discharge.
- Remind patient to bring her prescription bottle to her follow-up appointment, even if she has taken all of the medication.

Neonate Care/Postpartum Care

- Plan: After baby is born it is essential for mom to follow through with care for herself and baby.
- Care for Baby: Prior to being discharged from the hospital baby will be observed for a minimum of five to seven days after birth for Neonatal Abstinence Syndrome.
- Care for Mom: Mom in most instances will be discharged from hospital within three days of delivery. She is expected to be seen for a postpartum check by the OB/MOUD provider(s) at approximately two weeks, as well as, six weeks postpartum.

Addressing Patient Struggles, Relapse & Discontinuation of Treatment

- OBOT is a harm reduction model and therefore does not recommend automatic discharge for patients who struggle with substance use while engaged in medication treatment for addiction.
 - If return to pretreatment use occurs, the treatment plan should first be revised to increase monitoring and supports. In a case of continued use despite an intensified treatment plan, a patient may be referred to a higher level of care.
 - Clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office-based setting prior to referring to another level of care.
- Situations when the OBOT team may recommend more intensive levels of care:
 - Ongoing use despite adequate buprenorphine/naloxone dosing: no withdrawal symptoms and adequate opioid blockage.
 - Multiple negative buprenorphine UTS results for patients taking prescription buprenorphine.
 - Ongoing use of benzodiazepines, barbiturates, cocaine/stimulants, alcohol or other central nervous system depressants (gabapentin, quetiapine, clonidine, promethazine, etc.) causing impairment, sedation, overdose, medical events and/or hazardous unsafe behaviors despite interventions by the OBOT team.
 - Presenting intoxicated (i.e., under the influence of alcohol or other substances), incidence of overdose or hospitalization related to substance use.
 - The risk of continuing treatment outweighs the benefit.
- If the patient complies with the intensive treatment plan and has had some improvement in substance use, team will restructure treatment as needed and continue treatment with buprenorphine/naloxone.

Revision of Treatment Plan:

- More frequent visits.
- Shortened prescription intervals.
- Confirmation of counseling and team engagement with counselor.
- Referral to relapse prevention groups or individual therapy.
- Referral to IOP.
- Psychiatric evaluation and treatment per psychiatric assessment.
- Residential treatment.
- Increased collaboration with community providers.
- Family/support involvement.

Referral to Higher Level of Care

- Detoxification/CSS/TSS.
- Residential treatment.
- Opioid treatment program for methadone or daily observed buprenorphine.
- Dual diagnosis.

Buprenorphine/Naloxone: Relapse & Aberrant Urine Toxic Screen Results

- In all cases of an unexplained UTS (i.e., patient did not report substance use at visit or report inappropriate medication management at visit), the OBOT team will discuss revising the treatment plan and discuss with patient at next visit in an effort to address a potential return to pretreatment use or medication issue. Confirmations testing for buprenorphine and non-buprenorphine should be done at providers discretion.

Negative Buprenorphine

- If the patient provides adequate explanation regarding negative buprenorphine/naloxone to OBOT team, the OBOT team will establish a follow-up plan for the patient to return to clinic within one week.
- If the patient is unable to provide an explanation regarding negative buprenorphine/naloxone, the urine should be sent for confirmatory testing for buprenorphine and non-buprenorphine.
- Repeat UTS should be obtained and sent for confirmatory testing (i.e., buprenorphine level) that includes checking for the presence of buprenorphine's metabolite, norbuprenorphine.
- At return visit, the negative urine screen result is addressed.
 - Review medication administration and dosing schedule. Consider diversion and possible return to pre-treatment use.
 - Assess and modify treatment plan as needed. If the patient is struggling, return to weekly clinic visits and prescriptions.
 - The patient's buprenorphine/naloxone dose may need to be adjusted (i.e., increased if struggling, decreased if taking less than their prescribed dose). The entire OBOT team should be consulted prior to adjusting a patient's medication dose.
 - If the patient denies any reason for negative buprenorphine/naloxone and repeat is again negative, the patient may be referred to a higher level of care.
- Assess dose: If the dose is less than 4 - 6mg, urine may need to be sent for confirmatory testing due to the cut-off limits of the test and therefore its inability to react positive to buprenorphine.

Positive Opioids

- Report of opioid use or positive opioid toxicology screen result is addressed by OBOT provider during visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not admit using at the visit and denies use when addressed at next visit, the patient may be supervised at the following UDS collection.
 - A report of opioid use or a positive opioid UTS will result in intensification of the treatment plan potentially including increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide education on relapse prevention and overdose and send naloxone prescription to pharmacy. This includes the patient returning to weekly clinic visits until they are stable.
- If the patient has three to four consecutive weeks of positive opioid urines, the patient will be assisted with a transfer to a higher level of care.
 - Again, clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office-based setting prior to referring to another level of care.

Polysubstance Use

Cocaine

- Report of cocaine use or a positive cocaine UTS result is addressed by the OBOT provider during the visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not admit to use at the visit, urine should be sent for confirmatory testing.
- A report of cocaine use or a positive cocaine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly clinic visits until stable.
 - Contingency management combined with psychosocial support (CBT, counseling) has been shown to be an effective strategy for decreasing stimulant misuse and should be considered when possible.

Amphetamines

- Report of illicit amphetamine use or positive amphetamine UTS result is addressed by OBOT provider during visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UDS and does not admit to use at the visit, urine should be sent for confirmatory testing.

- A report of illicit amphetamine use or a positive amphetamine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly clinic visits until they are stable.
 - If the patient reports that they are struggling with attention deficit and/or hyperactivity, offer the patient a referral to psychiatry for evaluation.
 - If the patient reports diagnosis of ADHD and requests amphetamine medications, the patient should undergo a neuro-psych evaluation for a proper diagnosis.
 - Two to three positive UTS results for illicit amphetamine in a row may lead to further intensification of the treatment plan, such as referral to IOP and/or a relapse prevention group, other self-help, increased counseling, and/or increased OBOT visits.
 - Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

Benzodiazepines

- Benzodiazepines have known teratogenicity in the first trimester. Attempts to taper and discontinue are appropriate. Careful discussion of the risks and benefits of continued use is an important part of shared decision-making.
- Report of illicit benzodiazepine use or a positive benzodiazepine UTS result is addressed by the OBOT provider during the visit and the treatment plan is intensified accordingly to meet the needs of the patient.
 - If the patient has a positive UTS and does not admit to use at the visit, urine should be sent for confirmatory testing.
- A report of illicit benzodiazepine use or a positive benzodiazepine UTS will result in intensification of the treatment plan, relapse prevention education and overdose prevention education. This includes the patient returning to weekly clinic visits until they are stable.
 - If the patient reports they are struggling with anxiety, offer a referral to psychiatry for evaluation. Providers should make every effort to stay clear of benzodiazepines and other medications with potential for misuse.
- Urine samples will be sent for confirmatory testing and identification of the medication if positive for benzodiazepines twice in a row.
- Ongoing benzodiazepine misuse despite intensified treatment plan may result in referral to a higher level of care.

Presenting Impaired

Any patient who presents to the clinic intoxicated (i.e., under the influence of alcohol or any other substance) will require urgent team assessment, safety assessment and revision of their treatment plan. Additionally, if a patient who presents intoxicated is accompanied by a child or other dependent, please refer to your institution's policies regarding safety concerns and mandated reporting.

Diversion

In cases of suspected diversion (i.e., suspicious buprenorphine negative urines, requests for early refills, reports of lost/stolen/destroyed medication, requests for dose increase), the patient should be asked to come into the clinic for an urgent assessment. This assessment should include toxicology testing. When possible, confirmatory testing (i.e., via buprenorphine level) is recommended to confirm presence of buprenorphine and its metabolite norbuprenorphine.

Any patient known to be diverting buprenorphine will be evaluated by the treatment team to discuss appropriate next steps and possibly transitioned to a higher level of care.

Specific Populations

Methadone to Buprenorphine Transfers

During pregnancy a patient should not be switched from methadone to buprenorphine/naloxone.

Patients with HIV

Patient's that are pregnant with HIV should be seen by a HIV specialist.

- Buprenorphine/naloxone use does not interfere with clinical response to antiretroviral medications.
- Side effects from drug interactions between HIV medications and buprenorphine/naloxone are less severe/significant than those experienced with methadone.
- Reassure patients that treatment for their opioid use disorder will not interfere with their HIV disease management.

Considerations:

- Multiple protease inhibitors may affect levels of buprenorphine and norbuprenorphine, particularly ritonavir-containing regimens as this is a metabolic inhibitor.
 - Atazanavir and darunavir have been found to cause significant increases in buprenorphine and/or norbuprenorphine levels, potentially leading to sedation and cognitive impairment.
- Ritonavir is used as a metabolic inhibitor and can increase buprenorphine and/or norbuprenorphine levels, potentially leading to sedation and cognitive impairment.
- Lopinavir-containing regimens may be associated with decreased norbuprenorphine levels, potentially leading to withdrawal or cravings.
- These interactions do not contraindicate treatment but warrant close monitoring and potentially changing buprenorphine dosing.
- Some non-nucleoside reverse transcriptase inhibitors (NNRT's), particularly efavirenz, may decrease buprenorphine/naloxone levels and cause withdrawal symptoms.

- Closer monitoring is warranted and increasing buprenorphine dosing may be indicated.
- Buprenorphine/naloxone may slightly increase protease levels.
- Initiation of medication for opioid use disorder (MOUD) during HAART maintenance:
 - Clinical needs should determine treatment selection.
 - With opioid agonists, patients may benefit from a trial of buprenorphine/naloxone because of the more benign drug interaction profile of buprenorphine/naloxone compared with methadone.

Initiation of HAART During Buprenorphine/Naloxone Maintenance:

- Continue usual buprenorphine/naloxone dose.
- Check for medication interactions. <http://arv.ucsf.edu>
- Monitor as appropriate.

Patients with Hepatitis C

- Buprenorphine/naloxone is extensively metabolized by the liver.
- Most recent guidelines indicate that there are minimal concerns co-managing HCV and opioid use disorders utilizing buprenorphine/naloxone.⁴
- Current data suggests that liver injury from buprenorphine occurs rarely, however patients with hepatitis C are at higher risk of elevations in transaminases and reversible hepatic injury. Most of the evidence suggests that these elevations are related to underlying liver disease and not buprenorphine exposure. Serious hepatic injury is rare.
 - Buprenorphine maintenance may have indirect beneficial effect on liver health via reduction of illicit opioid use.
- A single-dose study of 43 patients compared buprenorphine/naloxone exposure in healthy individuals to persons with mild, moderate or severe hepatic impairment. Study results indicate that individuals with more advanced hepatic impairment experience higher exposure levels of naloxone vs buprenorphine when compared to healthy subjects.⁵
 - Dose adjustment may be required for some patients with severe liver disease.
 - May consider mono tablet in some cases of severe liver disease.
- There are a small number of case reports of intravenous use of buprenorphine/naloxone by patients with hepatitis C resulting in increased alanine aminotransferase levels to 30 to 50 times normal.⁵
 - Case reports of seven patients with hepatitis C using buprenorphine/naloxone who had increased ALT 39x normal.⁶
 - All continued buprenorphine/naloxone; 50% dose reduction in three patients.
 - All recovered without any clinical complications.
- When initiating buprenorphine/naloxone treatment it is important to do baseline hepatic testing and then retest transaminases as needed based on clinical assessment.
- MOUD prescriber can consult with infection disease provider if the prescriber is not comfortable.

Dual Diagnosis

Buprenorphine/Naloxone

- Buprenorphine/naloxone is metabolized in the liver by the cytochrome P450 3A4 system.
- Clinical experience has not uncovered significant drug-drug interactions with buprenorphine/naloxone.
- Dosing changes are generally not necessary, as opposed to methadone dosing, which is highly influenced by concomitant medication use.
- Reassure patients with comorbid psychiatric conditions that the use of buprenorphine/naloxone is not a barrier to treatment of their psychiatric condition.

Pain Management Protocol: Buprenorphine/Naloxone

Buprenorphine/Naloxone Patients Requiring Surgery

Background: These guidelines are designed for patients maintained on buprenorphine or buprenorphine/naloxone undergoing invasive procedures. There is currently a lack of evidence-based studies to direct the management of patients on buprenorphine/naloxone maintenance in the peri-procedure period. Below are guidelines using expert opinions based on pharmacological principles with the intent to avoid under-treatment of acute pain while also avoiding potential opioid withdrawal and disruption of opioid use disorder treatment. The appropriate treatment of acute pain in patients on buprenorphine/naloxone maintenance includes continuing the patient's baseline opioid requirements to avoid increased pain sensitivity associated with opioid withdrawal. Daily opioid maintenance treatment requirements must be met before attempting to achieve analgesia. These patients have also been shown to have increased pain sensitivity and cross-tolerance to opioid analgesics, therefore adequate pain control may necessitate higher opioid doses at shorter dosing intervals. All patients on buprenorphine/naloxone maintenance should be co-managed with their buprenorphine/naloxone provider during the pre- and post-procedure periods.⁷

Buprenorphine: Peri-Procedure Management

Recommendations:

- Daily buprenorphine/naloxone dosing remains uninterrupted. Patient takes usual buprenorphine/naloxone maintenance dose on the morning of procedure.
 - Because of its high affinity at the opioid receptor, consider fentanyl as the opioid of choice for analgesia during procedures and in the PACU for these patients.
- Continue patient's home dose of buprenorphine/naloxone post-operatively.
 - Consider splitting the patient's usual buprenorphine/naloxone dose into every eight-hour dosing (e.g., 24mg per day changed to 8mg every eight hours).
- If further pain control is needed, begin by utilizing multimodal pain management with non-opioids (NSAIDs, acetaminophen, lidocaine patches, etc.).
- Consider the use of local and regional anesthesia as indicated.

- If opioids are needed for breakthrough pain, standard dosing protocols should initially be utilized with careful monitoring and the understanding that patients with a history of OUD may require higher than usual doses due to cross tolerance and increased pain sensitivity.
- PCA's without a basal component may be considered in addition to a patient's buprenorphine if the pain is not adequately captured. If a PCA is utilized, discontinue oral PRN opioids.
- The buprenorphine/naloxone provider should be contacted pre-and post-procedure to assist in ongoing assessment, support and pain management.
- Schedule patient to be seen by their buprenorphine/naloxone prescriber within one-week post procedure.

Buprenorphine: Acute and Chronic Pain Management

General principles for pain management on buprenorphine/naloxone:

- Patients physically dependent on opioids require maintenance on daily equivalence before any pain relief is achieved with opioid analgesics (the "opioid debt").
 - Evidence-based data now supports continuing patients on their daily maintenance dose of buprenorphine/naloxone during periods of acute pain, rather than discontinuing and later restarting buprenorphine treatment. Maintaining buprenorphine/naloxone has been shown to increase pain control while allowing the patient to remain stabilized on their medication treatment for OUD.
- Reassure patients that their addiction will not be an obstacle to aggressive pain management.
- Include patients in decision-making processes to alleviate anxiety.
- Establish clear goals for pain management.
- Promote pain reduction rather than elimination.
- Reach for improved function.
- Address associated symptoms.
- Use a multimodal approach to pain management:
 - Consider splitting the patient's usual buprenorphine/naloxone dose into every six- or eight-hour dosing (e.g., 24mg per day changed to 8mg every eight hours).
 - Try non-opioids and adjuvant therapies. (Examples include: Acupuncture, acupressure, massage, physical therapy, hydrotherapy, mindful meditation, NSAIDs, acetaminophen, topical lidocaine, SSRI, TCAs, etc.)
 - Consider a modest increase in patient's buprenorphine/naloxone maintenance dose.
- Use opioid analgesics as the last option.
- If opioid analgesics are necessary for treatment of chronic pain, buprenorphine/naloxone should be discontinued and methadone maintenance initiated.

Sampling of the Evidence:

- Macintyre et al., (2013) performed a retrospective cohort study comparing pain relief and opioid requirements in the first 24 hours after surgery in 22 patients maintained on buprenorphine and 29 patients maintained on methadone, who were also prescribed patient-controlled analgesia. The study found no significant differences in pain scores, incidence of nausea or vomiting requiring treatment, or sedation between the buprenorphine or methadone maintained patient groups overall. Additionally, it was found that buprenorphine-maintained patients who were not given their usual buprenorphine dose the day after surgery used significantly more: Patient-controlled analgesia ($P=0.02$) compared with those who had received their dose.⁸
- Kornfield and Manfredi (2010) performed a literature review examining five buprenorphine-maintained patients who underwent seven planned major surgical procedures with high levels of anticipated post-operative pain (right-side colectomy, small bowel resection, L and R knee replacements, bilateral mastectomy, breast reconstruction, X-Stop procedure). In all seven cases, daily buprenorphine maintenance dosing was uninterrupted. Full agonist opioids and non-opioid analgesics were used in conjunction with daily buprenorphine dosing. In all seven surgical cases, good to excellent pain control was achieved.⁹
- Silca & Rubenstein (2016) presented a case comparing two different outcomes for the same surgical course performed at two different times on the same chronic pain patient. Results showed that pain control was easier to achieve and functional recovery was greater when buprenorphine was maintained throughout the perioperative period when compared with using a full mu agonist opioid for chronic pain perioperatively.¹⁰

Appendix 1

Acronyms

ACOG: American College of Obstetricians and Gynecologists

BSAS: Bureau of Substance Abuse Services

CFR-42: Code of Federal Regulations, Title 42

CNM: Certified Nurse Midwife

CNS: Central Nervous System

CSAT: SAMHSA's Center for Substance Abuse Treatment

CSS: Clinical Stabilization Services {short-term inpatient stabilization}

DATA 2000: Drug Addiction Treatment Act of 2000

DEA: US Drug Enforcement Agency

DCF: Department of Children and Families

DSM: Diagnostic and Statistical Manual of Mental Disorders

FDA: Food and Drug Administration

HCG: Human Chorionic Gonadotropin

HIPAA: Health Insurance Portability and Accountability Act

IOP: Intensive Outpatient Program {counseling}

LFT: Liver Function Test

MOUD: Medication for Opioid Use Disorder

NAS: Neonatal Abstinence Syndrome

NSAID: Non-steroidal Anti-inflammatory Drug

NSDUH: National Survey on Drug Use and Health OB: Obstetrics

OBOT: Office Based Opioid Treatment

OD: Opioid Use Disorder

OTP: Outpatient Treatment Program (daily medication administration treatment)

PCA: Patient Controlled Analgesia

PDMP: Prescription Drug Monitoring Program

TSS: Transitional Stabilization Services (inpatient "holding" facility)

UTS: Urine Toxicology Screen

Appendix 2

Record: ACKNOWLEDGMENT OF OPIOID START TALKING

(MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD)

Michigan Department of Health and Human Services

Patient Name		Date of Birth
Name of Controlled Substance Containing An Opioid		
Dosage	Quantity Prescribed (for a minor, if signature is not the parent or guardian, the prescriber must limit the opioid to a single, 72 hour supply).	
Number of Refills		
<p>A controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse. My provider shared the following:</p> <ul style="list-style-type: none"> a. The risks of substance use disorder and overdose associated with the controlled substance containing an opioid. b. Individuals with mental illness and substance use disorders may have an increased risk of addiction to a controlled substance. (Required only for minors.) c. Mixing opioids with benzodiazepines, alcohol, muscle relaxers, or any other drug that may depress the central nervous system can cause serious health risks, including death or disability. (Required only for minors.) d. For a female who is pregnant or is of reproductive age, the heightened risk of short and long-term effects of opioids, including but not limited to neonatal abstinence syndrome. e. Any other information necessary for patients to use the drug safely and effectively as found in the patient counseling information section of the labeling for the controlled substance. f. Safe disposal of opioids has shown to reduce injury and death in family members. Proper disposal of expired, unused or unwanted controlled substances may be done through community take-back programs, local pharmacies, or local law enforcement agencies. Information on where to return your prescription drugs can be found at http://www.michigan.gov/deqdrugdisposal. g. It is a felony to illegally deliver, distribute or share a controlled substance without a prescription properly issued by a licensed health care prescriber. 		

continued >

MDHHS-5730 (4-18a)

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DO NOT MARK BELOW THIS LINE



I acknowledge the potential benefits and risks of an opioid medication as described by my provider along with the responsibility of properly managing my medication as stated above.	
Signature of Prescriber (when prescribing to a minor).	Date
Signature of Patient (if a minor, patient's parent/guardian).	Date
Signature of Patient's Representative or Other Authorized Adult.	Date
Printed Name of Parent/Guardian; Patient's Representative or Other Authorized Adult.	
<p>The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.</p>	<p>AUTHORITY: PCA 246 of 2017, MCL 333.7303b and MCL 333.7303c</p> <p>COMPLETION: Required.</p> <p>PENALTY: Probation, limitation, denial, fine, suspension, revocation or permanent revocation.</p>

Consent: CONTROLLED SUBSTANCE THERAPY

Patient Name	Date of Birth
MRN	
Physician	
FIN	

My primary provider (physician/clinic) for controlled substances is: _____

What is this agreement about?

- Information about controlled substance medicine.
- Following a safe treatment plan.
- Making sure state and federal laws are followed regarding controlled substances.
- Rules to follow when receiving controlled substances.

What do I need to know when I take controlled substance medication for a long time?

- I could become dependent on the medication. If I stop the medicine suddenly, I could have uncomfortable or dangerous withdrawal symptoms.
- I may develop serious constipation. I could have trouble urinating.
- I may have drowsiness, nausea, itching and trouble sleeping – not enough or too much.
- It could affect my sexual function.
- It can slow my breathing.
- It may be dangerous if I take more medicine than my primary provider ordered or if mixed with alcohol. This could result in damage to my organs or even death.
- If I become pregnant, it can cause serious risks to my unborn baby.

continued >

White - Chart		Yellow - Patient	
DO NOT MARK BELOW THIS LINE		DO NOT MARK BELOW THIS LINE	
BARCODE ZONE		BARCODE ZONE	
			

RULES FOR CONTROLLED SUBSTANCE THERAPY

1. I can get refills for my controlled substance medicine only from my primary provider.
2. I will not be able to get a refill or prescription for controlled substance medication from any other provider, urgent care, or emergency room
3. I will request a refill prescription for my controlled substance medicine during business hours Monday through Friday. I will NOT be able to get a refill on the weekends and after hours.
4. My primary provider may get information about me from any pharmacist or my referring doctor about my use of medicines. I will tell my primary provider about any other medicines or substances I am taking. I will not take any prescription medicines that are not prescribed for me.
5. I will tell my primary provider (or another one who has been assigned) about any side effects with controlled substance and pain-related medicines. If I have a serious side effect after hours or on the weekend, I may contact my primary provider's office on-call answering service. I may also seek treatment at an urgent care center or the emergency room.
6. I will take my controlled substance medication exactly as ordered by my primary provider. I will not change the dose or time schedule unless my primary provider says to do so.
7. I will not use any illegal controlled substance.
8. I will tell my primary provider if I choose to participate in the Michigan Medical Marijuana Program. I understand my primary provider may choose to no longer prescribe controlled substances for me. My primary provider may need to safely wean me from the controlled substance.
9. I will be responsible for my medicine. I will not sell, trade, or share any controlled substance medicine. I understand my primary provider will not replace any lost, forgotten or stolen medication.
10. I will keep my follow-up appointments. If I do not, I understand my primary provider may not provide any more prescriptions for controlled substances and may also discharge me from the practice.
11. My primary provider will evaluate me on a regular basis to see if this treatment benefits me.
12. My primary provider may request a drug screen to check for other medicines and substances. I agree to a pill count if I am asked.
13. If female: I must not currently be pregnant. I must agree to inform my primary provider if I become pregnant, if I am attempting to become pregnant or if I am engaging in unprotected sex (and am of child-bearing age).

AGREEMENT

- I have read this form or had it read to me in words I can understand.
- I understand and agree to the rules described above.
- If I do not follow the rules I know I may not receive any more prescriptions for controlled substances. I may also be dismissed from the practice.
- I also understand the side effects of controlled substances. If I still have questions, I will ask my primary provider for written information on the side effects of the controlled substances that the provider is prescribing for me.

continued >

Below are signatures for patient or parent/guardian (if patient is under 18 years of age) and witness.

Time _____ Date _____ Patient Signature _____

Time _____ Date _____ Parent/Guardian Signature _____

Time _____ Date _____ Witness Signature _____

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language,
_____, all oral presentations made by all of those present
during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

Consent: GENERAL, TREATMENT AND RELEASE OF INFORMATION

Patient Name (printed)	Medical Record Number
Account Number	Date

NOTICE OF NONDISCRIMINATION

Spectrum Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Spectrum Health does not exclude people or treat them differently because of race, color, national origin, age, disability or sex. See pages 3 and 4 for the complete notice of nondiscrimination as well as availability of language assistance.

I agree:

- To examination and treatment by doctors and other healthcare professionals at Spectrum Health including Telemedicine.
- That the doctor may change my care to benefit my life or health.
- If I am here to give birth, the doctor and other healthcare professionals may give care to my baby.

I understand that:

- I will ask questions.
- No one has made promises about the results of my treatment or care.
- Students and staff may see me and look at my medical record for teaching or research purposes.
- The staff will double-check who I am. They will ask what I am having done. This is to protect me.
- Some doctors and staff are not employees of Spectrum Health. I know that Spectrum Health is not responsible for their care or other actions. I also know I will receive separate bills from them even though they provide services to me at a Spectrum Health location. I will work with their offices to answer questions about my insurance.
- Michigan law allows healthcare providers to test my blood for HIV (AIDS virus) or Hepatitis without my consent if someone who has helped in my care is exposed to my blood or body fluids.
- A copy of the Spectrum Health Financial Assistance Eligibility Policy is available upon request at all registration areas and on our website at www.spectrumhealth.org.
- Spectrum Health will not tolerate discrimination against my doctor, other healthcare professionals or staff because of race, color, gender, national origin, age, disability, sex or any other basis prohibited by federal, state or local law.

continued >

My Medical Information.

- SPECTRUM HEALTH MAY RELEASE MY MEDICAL INFORMATION TO:
 - Insurance companies, health plans and administrators for payment of services I receive.
 - Government agencies like Medicare and Medicaid or as required by law.
 - My doctors and others involved in my care now or in the future.
 - My employer, if the records are related to care or services paid for by my employer, or for other purposes that are allowed under law.
 - Any person or entity responsible to pay all or part of my bill.
- I agree that Spectrum Health can take my picture and save it to my electronic medical record. I understand that Spectrum Health will use this picture for identification purposes with the goal of improving my patient experience as I move throughout the Spectrum Health system.
- I understand Spectrum Health will keep my medical information according to State law, Federal law and policy. I also understand that my medical information may be stored electronically and may be sent to or received from other healthcare providers and/or payers electronically. This includes my diagnosis (what is wrong with me), treatments (what we are doing to make me better), and medicine or prescription information about my mental health, infectious diseases like HIV, and other problems like drug or alcohol use may be included.
- In some cases, Spectrum Health is required by law to report medical information to an agency like the health department. This may include information about HIV, TB and other diseases.

Privacy Notice.

- I have rights and responsibilities when I receive services. Spectrum Health has given me its Notice of Privacy Practices, and I have had an opportunity to ask questions about the information in the Notice.

Valuables.

- Spectrum Health would like its patients to leave valuables at home or with family members. I agree Spectrum Health is not responsible for safeguarding my property.

Consent to Call.

- I have provided residential and/or cellular telephone numbers and an email address to Spectrum Health. I consent to receive auto-dialed and/or pre-recorded telephone calls, text messages and/or emails from Spectrum Health and/or its agents/third parties at any of these phone numbers for communication including billing purposes. I understand that my consent to call is not a condition of my treatment.

Authorization to Receive Payment.

- Spectrum Health is authorized to act on my behalf in the collection of benefits from any third party and in the endorsement of checks payable to me and/or Spectrum Health. I understand that Spectrum Health is authorized to seek payment from any third party and from me.

continued >

Assignment.

- I assign Spectrum Health:
 - All benefits, claims, and any and all other rights, including the right to bill and talk to any third party for the purpose of seeking payment.
 - The right to file suit or intervene in any lawsuit or proceeding which involves my charges at Spectrum Health.
 - The right to take any other action seeking payment of my Spectrum Health charges.
- This assignment includes, but is not limited to, the right to appeal the denial of payment of my Spectrum Health charges from any payer, including any employer-sponsored benefit plan, insurance policy or insurance coverage provided by law or contract. I authorize Spectrum Health to act on my behalf to pursue an ERISA benefit claim or to appeal an adverse benefit determination. I agree to assist Spectrum Health in the pursuit of all insurance benefits and agree to pay all co-insurance, co-payments and deductibles required by any insurance plan.
- I also assign to Spectrum Health, and agree that I waive, any and all rights to settle, release or retain payment of my Spectrum Health charges, or take any other action which would in any way compromise payment or reimbursement of my Spectrum Health charges.

Billing.

- I authorize any insurance company, responsible for payment of my medical care and treatment, to pay Spectrum Health for the services given. I understand that I am responsible for any charges not covered by insurance.
- I agree that if my account is not paid when due, and the hospital should retain a lawyer and/or collection agency for collection, I will be responsible to reimburse the hospital for all costs, charges and fees associated with the collection of the amount due including, but not limited to, reasonable interest, legal costs in the event suit is filed and reasonable lawyer fees and/or reasonable collection agency fees including those based on a percentage of the debt.

Patient Signatures.

I have read this form and I understand it. All my questions have been answered.

Time _____ Date _____ Patient Signature _____

Patient is under 18 years of age or otherwise unable to consent because _____

Time _____ Date _____

Parent/Legal Guardian/Patient Advocate/Next of Kin Signature _____

Printed Name _____

continued >

Staff Signatures.

Time _____ Date _____ Witness _____

Second witness needed for verbal consent.

Time _____ Date _____ Witness _____

Interpretation Services.

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

continued >

Consent: GENERAL, TREATMENT AND RELEASE OF INFORMATION

Patient Name (printed)	Medical Record Number
Account Number	Date

Notice of Nondiscrimination:

Spectrum Health complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. Spectrum Health does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

SPECTRUM HEALTH:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters.
 - Written information in other formats (large print, audio, accessible electronic formats, other formats).
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters.
 - Information written in other languages.

If you need these services, contact Spectrum Health Language Services at 616.267.9701, 1.844.359.1607 (TTY:711).

If you believe that Spectrum Health has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex:

- You can file a grievance with:

Director, Patient Experience

100 Michigan Street NE, MC 006

Grand Rapids, MI 49503

616.391.2624 or toll free: 1.855.613.2262

patient.relations@spectrumhealth.org

You can file a grievance in person, by mail or by email. If you need help filing a grievance, the Director of Patient Experience is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services

200 Independence Avenue SW, Room 509F, HHH Building

Washington, DC 20201

1.800.368.1019 or 1.800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

continued >

Contact Us.

Español (*Spanish*)

ATENCIÓN: Si usted habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-844-359-1607 (TTY: 711).

العربية (*Arabic*)

ملحوظة: إذا كنت تتحدث أذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-844-359-1607 (رقم هاتف الصم والبكم: 711).

中文 (*Chinese*): 國語/普通話 (*Mandarin*), 粵語 (*Cantonese*)

請注意：如果您講中文，您可以獲得免費的語言輔助服務。請撥打1-844-359-1607（TTY 手語翻譯：711）。

Tiếng Việt (*Vietnamese*)

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-844-359-1607 (TTY: 711).

Ako govorite srpsko (*Serbian, Croatian or Bosnian*)

OBAVJEŠTENJE: Ako govorite srpsko-hrvatski, usluge jezičke pomoći dostupne su vam besplatno. Nazovite 1-844-359-1607 (TTY: 711). (TTY-Telefon za osobe sa oštećenim govorom ili sluhom: 711).

አማርኛ (*Amharic*)

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ፡ 1-844-359-1607. (መስማት ለተሳናቸው፡ (TTY: 711).

नेपाली (*Nepali*)

ध्यान दिनुहोस्: तपाईंले नेपाली बोल्नुहुन्छ भने तपाईंको निम्ति भाषा सहायता सेवाहरू निःशुल्क रूपमा उपलब्ध छ । फोन गर्नुहोस् 1-844-359-1607 (टिडिवाइ: (TTY: 711).

Thuɔŋjaŋ (*Nilotic – Dinka*)

PIŋ KENE: Na ye jam në Thuɔŋjaŋ, ke kuony yenë koc waar thook atö kuka lëu yök abac ke cín wënh cuatë piny. Yuopë 1-844-359-1607 (TTY: 711).

Kiswahili (*Swahili*)

KUMBUKA: Ikiwa unazungumza Kiswahili, unaweza kupata, huduma za lugha, bila malipo. Piga simu 1-844-359-1607 (TTY: 711).

فارسی (*Farsi*)

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 1.844-359-1607 (TTY: 711) تماس بگیرید.

Français (*French*)

ATTENTION: Si vous parlez français, des services d'aide linguistique-vous sont proposés gratuitement. Appelez le 1.844-359-1607 (TTY: 711).

(*Burmese*)

အသိပေးခြင်း

သင်ပြောသော ဘာသာစကားကို အခမဲ့ ဘာသာပြန်
ရှိပါသည်။ ဖုန်းခေါ်ရန်

فارسی دری (*Dari*)

توجه اگر به زبان دری صحبت می کنید، خدمات کمک زبانی بصورت رایگان برای شما در دسترس است. تماس ب 1-844-359-1607 (TTY: 711).

Kreyòl Ayisyen (*Haitian Creole*)

ATANSYON: Si ou pale Kreyòl Ayisyen, gen èd nan lang ki disponib gratis pou ou. Rele nimewo 1-844-359-1607 (TTY: 711).

continued >

Contact Us.

Ikinyarwanda (*Kinyarwanda*)

ICYITONDERWA: Niba uvuga ikinyarwanda, serivisi z'ubufasha ku byerekeye ururimi, urazihabwa, ku buntu.

Hamagara 1-844-359-1607 (ABAFITE UBUMUGA BW'AMATWI BIFASHISHA ICYUMA CYANDIKA -TTY: 711).

Soomaali (*Somali*)

DIGTOONI: Haddii aad hadasho Soomaali, adeegyada caawimada luqadda, oo bilaasha, ayaad heli kartaa. Wac 1.844-359-1607 (TTY: 711).

اللغة السودانية (*Sudanese*)

انتباه: إذا كنت تتحدث اللغة السودانية، خدمات المساعدة بلغتك متاحة مجاناً. اتصل على الأرقام 1-844-359-1607 (رقم الصم والبكم: 711).

தமிழ் (*Tamil*)

கவனம்: நீங்கள் தமிழ் பேசினால், உங்களுக்கு இலவசமான மொழி உதவிச் சேவைகள்

கிடைக்கின்றன.இந்த எண்ணை அழைக்கவும்: 1-844-359-1607 (TTY: 711).

ትግርኛ (*Tigrinya*)

ትኩረት: ትግርኛ ኢንጅር ትላረብኩን፣ ናይታዕታይ ደገፍ ኣለዎለዎን፣ ብጽኢ ክቕርብኩክ ኣየግብኩም፣ ደዊኩ 1.844-359-1607 (TTY: 711)።

**Record/Consent: RECORD OF AGREEMENT AND UNDERSTANDING OF/
CONSENT TO PARTICIPATE IN THE BUPRENORPHINE TREATMENT PROGRAM -
MEDICAL GROUP**

Patient Name	Date of Birth
MRN	
Physician	
FIN	

RECORD OF AGREEMENT AND UNDERSTANDING

I agree:

FOR ALL OF MY SCHEDULED APPOINTMENTS:

- To go to each appointment.
 - If I know I can not make it to the appointment, I will call the clinic at once to cancel. I will reschedule another appointment to make up for the canceled one.
 - If I have an emergency and I can't make it to the appointment, I will call the clinic to reschedule another appointment.
 - If I have a schedule change that conflicts with many of my scheduled appointments, I will call the clinic as soon as I know. The clinic will try to reschedule appointments.
 - If I have too many missed appointments, I may have to be given my medicine(s) more often. I may have to be referred to a higher level of care.
- To be early or on time to each appointment. I will call the clinic as soon as possible if I am running late.
- To be courteous while I am in the clinic. I will not act in a threatening or disruptive way.
- To not be intoxicated or under the influence of drugs when I come to the clinic. If I am, the clinic may refuse to see me, and my treatment plan will have to be changed.
- To not do any illegal activities in the clinic or on the hospital campus. If this happens, I may be immediately kicked out of the program. Refer to the policy "Dismissing a Patient from a Physician Practice" for specific information.

continued >

DO NOT MARK BELOW THIS LINE BARCODE ZONE DO NOT MARK BELOW THIS LINE



I agree: (continued)

TO SAFEGUARD ALL MY MEDICINE(S). THIS MEANS I WILL:

- Take all of my medicine(s) as the prescription bottle instructs.
- Keep my medicine(s) in the bottle that has the prescription label on it.
- Be responsible and keep all of my medicine(s) in a safe and secure place.
- Not keep medicine(s) in areas where someone may be able to see/take them.
- Not keep them in shared areas in the home, at work or out in public places.
- Not keep medicine(s) where children may see or take them.
- Not sell, share or give any of my medicine(s) to another person. This is a serious violation of the agreement for treatment in this program and I may be referred to a higher level of care.

TO TELL THE CLINIC ABOUT ANY CHANGES OF INFORMATION
AS SOON AS POSSIBLE. THIS INCLUDES:

- Any phone number(s).
- All contact information (e.g., address, email, etc.).
- Any change or addition of a pharmacy. I will tell the clinic the pharmacy name, address, phone number.
- I agree to participate in all aspects of the Buprenorphine Treatment Program. Taking buprenorphine is only one part of my treatment. Education, counseling and relapse prevention programs are all available to help me in my treatment.
- To have a phone that works at all times. This is for the random check calls. The clinic must have my phone number on record.
- To tell the clinic immediately if I get additional medicine(s) from any doctors, pharmacies or other sources.
- To not tamper or alter urine screen results. If I do, I may be referred to a higher level of care.
- To not eat poppy seeds while in this treatment program. Poppy seeds may cause me to test positive for opioids.
- To be honest with my treatment team if I am struggling. The clinic is here to help me in my treatment.

I understand:

- My treatment team in the Buprenorphine Treatment Program wants to be able to help lessen your need for opioids. Buprenorphine is known as a partial opioid agonist which means it partially works like an opioid and the effect is weaker than full agonists like heroin and methadone.
- If my appointments are canceled often, I may be transferred to a more intense treatment option.
- ABOUT BUPRENORPHINE:
 - Any lost medicine(s) will not be replaced for any reason. This is a controlled substance.
 - Mixing buprenorphine with other substances can be very dangerous (especially those which can cause drowsiness such as benzodiazepines or alcohol). It can cause death.
 - If I misuse other illicit substances or medicines, my treatment team will discuss with me. My treatment plan will change in order to help me. If I continue to struggle with ongoing substance use, I may be referred to a higher level of care.

continued >

I understand: (continued)

- Spectrum Health uses the State Prescription Monitoring Program (PDMP) to review my medicine profiles. This shows if am getting controlled substances from other providers. If Spectrum Health finds I get prescriptions from other providers, they will review this information. If those medicines are found to violate this treatment agreement, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.
- **ABOUT MY URINE SCREENS:**
 - The Buprenorphine Treatment Program does not have a chain-of-custody (a documented paper trail to ensure integrity of the sample) of urine toxicology screens. The purpose of my urine screens are for my treatment at Spectrum Health only. If I need to have a urine screen for legal purposes or program requirements, I must get urine screen outside of this program.
- If my urine tests positive for opioids, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.
- If my urine screen tests negative for buprenorphine, the clinic will evaluate the situation and talk to me about it. I may be referred to a higher level of care.

I understand:

- If I am discharged from this program, I may be reconsidered at a future time.
- My medical information, treatment plan and record of medical care will be kept in an electronic medical record (EMR). Healthcare professionals who are involved in my care at Spectrum Health will be able to see my EMR. Spectrum Health only reviews my records as law and policy allows.

PREGNANT WOMEN

The Buprenorphine Treatment Program is designed to help me. If I become pregnant, it is important for me to also think about the health and well being of my baby. My treatment team can help both my baby and me during this time. Since buprenorphine is a partial opioid agonist, it may effect your baby. Buprenorphine is a prescribed medicine and is not an illegal substance. Taking buprenorphine while pregnant is still better than relapsing and/or using illegal substances. Here is some helpful information below.

I understand:

- My baby may be born with neonatal abstinence syndrome. This is when newborn babies experience withdrawal from opioids. If I deliver at Spectrum Health, I understand my baby will stay in the hospital for five days to be observed for signs of withdrawal (longer if the baby's treatment team decides it is necessary). This is in the best interest of my baby and myself. I will follow the expectations above when working with the providers caring for my baby in the NICU.
- Child Protective Services (CPS) role is to protect the health and safety of a child. Just because I participate in the Buprenorphine Treatment Program does not mean CPS will be involved. There are ways they may become involved:
 - If I use non-prescribed substances, I may be referred to CPS.

continued >

I understand: (continued)

- If I am using non-prescribed substances around or after 20 weeks of being pregnant, those non-prescribed substances can be detected in my baby's first poop (meconium). Meconium is the dark green substance forming the first feces of a newborn infant. This meconium can be tested after birth. If it tests positive for non-prescribed substances, it must be reported to CPS. Buprenorphine is a prescribed medicine and is not a non-prescribed substance.
- My care providers are required to report information to CPS. They are not making a personal judgment about you. They must follow the law.

CONSENT TO PARTICIPATE

I agree to participate in the Buprenorphine Treatment Program.

I have read this form or it has been explained to me. All my questions about this form have been answered.

Time _____ Date _____ Patient Signature _____

Time _____ Date _____ Witness Signature _____

If a patient is under 18 years of age or otherwise unable to consent, the following must be completed:

I, _____, hereby certify that I am the _____
of the patient; that patient is unable to consent because patient is a minor, or because:

Time _____ Date _____

Parent/Legal Guardian/Patient Advocate/Next of Kin Signature _____

Time _____ Date _____ Witness Signature _____

Interpretation Services.

I certify that I have interpreted, to the best of my ability, into and from the participant's stated primary language, _____, all oral presentations made by all of those present during the informed consent discussion.

Time _____ Date _____ Interpreter Signature _____

Interpreter Name (print) _____

Job Breakdown: AMBULATORY STANDARD WORK

Essential Steps (check all that apply):		SWEAT Document Number: 10056 v3	SWEAT Revision Date: 07.30.2019
	Delivery System		
x	Service Line(s), list: All Ambulatory/HOD		
	Department(s), list:		
Customization Applicable to Site:		Site Number:	Implementation Date:
Workflow Title: Urine Drug Screen (UDS) Point of Care Testing		Why is this Standard Work Important? To ensure that urine drug screens are processed correctly.	

STEP	WHO Scope of Practice	WHAT Major Steps	HOW Key Points	WHY System & Regulatory Requirements				LINKS
				Patient Experience	Safety	Quality	Policy	
1	Clinical Team Member	During chart prep, MA will pend POCT DRUG SCREEN (Alere DX 14 ICUP) {POC 525} standing order.	<ul style="list-style-type: none"> Once patient is checked in, release UDS order. 	x	x	x		
2	Clinical Team Member	Place bluing tablet in the toilet in and tank. Then obtain Alere iCup and testing lid.	<ul style="list-style-type: none"> Bluing Tablet Lawson #83577. Alere iCUP Lawson #17992. If toilet is an automatic flush find out from facilities, if they can turn off the auto flush to make it a manual flush. Call has to be placed to facilities (ICCB puts tape over sensor). 	x	x			
3	Clinical Team Member	Instruct patient to wash their hands.	<ul style="list-style-type: none"> Have patient wash their hands prior to collecting specimen. This step must be observed by the Clinical team member. 	x	x	x		
4	Clinical Team Member	Give patient the Alere iCup.	<ul style="list-style-type: none"> Label the specimen according to the link. Instruct the patient to hand the specimen directly to clinical team member after they urinate into the specimen cup. Instruct patient that after specimen is received, to flush the toilet and wash their hands. Do not use restroom pass through. This ensures an accurate temperature. 	x	x	x	x	Labeling Policy #9955

continued >

5	Clinical Team Member	Begin processing specimen.	Complete the following in front of the patient: <ul style="list-style-type: none"> • Take the urine directly from the patient. • Verify the temperature, by looking at the dual temperature strip label on the iCUP. • Secure the test device cap on the Alere iCUP. 	x	x	x		
6	Clinical Team Member	Turn the cup on its side to activate testing.	<ul style="list-style-type: none"> • Note: A minimum of 30ml's are required for the test. • Refer to link. 	x	x	x	x	Urine Drug Screen iCUP Policy
7	Clinical Team Member	Set the timer for five minutes. Then either place or clip the timer to pocket.	<ul style="list-style-type: none"> • DO NOT interpret UDS results after eight minutes, as any results after eight minutes is invalid. • NO EXCEPTIONS! • Refer to link. 	x	x	x	x	Urine Drug Screen iCUP Policy
8	Clinical Team Member	Escort patient.	<ul style="list-style-type: none"> • Escort patient to exam room and finish rooming process following the standard workflow OR exit door if visit is complete. 	x	x	x		
9	Clinical Team Member	When timer alarms, return to specimen to complete interpretation.	Interpretation: <ul style="list-style-type: none"> • Negative = Colored lines appear in both the control and test region. • Positive = Colored lines appear in the control region and NO lines appear at a specific drug test region. • Invalid = NO lines appear in the control region. • Review Image in link. 	x	x	x	x	Urine Drug Screen iCUP Policy
10	Provider/ Clinical Team Member	Document results in patient's chart.	<ul style="list-style-type: none"> • Open patient's chart and document the test results in EPIC. • Document Temperature in comments section. • VERBALLY notify provider of any unexpected results.* • Notify Provider of UDS results, only after results have been entered into the patient's chart. NO EXCEPTIONS. 	x	x	x		
11	Provider/ Clinical Team Member	Send urine specimen to lab for confirmation if provider orders a test.	<ul style="list-style-type: none"> • Order Confirmation test (TARGET 32), clinical team member will process specimen and send to the lab. 	x	x	x		

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Good Care for You and Your Baby While Receiving Opioid Use Disorder Treatment.

STEPS FOR HEALTHY GROWTH AND DEVELOPMENT

Introduction.

If you have an opioid use disorder (OUD), receiving the right medicine along with counseling and recovery support services is important at all stages in your life. From pregnancy to delivery to caring for your baby, addressing your OUD and taking care of yourself is a continuous process. You will be better able to protect and care for your baby with a focus on creating and updating your treatment plan and getting the support you need. In all situations, your commitment to treatment and recovery will go a long way.

After your pregnancy, the actions you take or don't take matter. Below are some important things to know about OUD and caring for your baby, as well as, the do's and don'ts for creating a healthy environment for your family.

Things to Know.

- Birth control is important to prevent pregnancies you do not want, as well as, to ensure proper space between pregnancies.

Talk to your healthcare professionals about the full range of birth control options, including long-acting reversible contraception and the best birth control options while you are breastfeeding.

- Breastfeeding is healthy for you and your baby, so you should continue breastfeeding as long as possible. The amount of OUD medicine that passes into breastmilk is extremely small. Talk with your healthcare professionals to find out what is best for you and your baby.
- You may need additional treatment and support to help with your recovery. It is important to seek help early! To find a treatment provider in your area, visit www.samhsa.gov/find-help.
- Join a support group:

LifeRing: <https://lifering.org>

Mothers on Methadone: www.methadonesupport.org/pregnancy.html

Narcotics Anonymous: www.na.org

Secular Organizations for Sobriety (SOS): www.sossobriety.org

SMARTRecovery: www.smartrecovery.org

Young People in Recovery: www.youngpeopleinrecovery.org

Medicine Dose.

Now is a good time to ask your OUD treatment professionals to check your medicine dose. An effective dose during pregnancy may be too high or too low once your baby is born. It is normal to feel tired and stressed, but if these feelings are causing you to have cravings or urges to use opioids again, tell your healthcare professionals.

DO

DO schedule a follow-up visit with your healthcare professionals as soon as possible after you leave the hospital.

DO talk to your healthcare professionals before starting or stopping any medicines.

DO talk to your healthcare professionals about birth control and family planning.

DO continue breastfeeding for as long as possible and ask for support if you need it.

DON'T

DON'T change the type of OUD medicine right after deliver.

DON'T hesitate to ask for help when you are feeling stressed or depressed.

DON'T be afraid to tell your healthcare professionals that you are having cravings or urges for opioids.

What to expect when you meet with healthcare professionals about OUD treatment while caring for your baby.

If your medicine is no longer working and you feel sleepy or are tempted to start using again, your healthcare professionals can help. Be honest about any cravings or urges you may have to use opioids. The stress that comes with being a new mother may increase these urges.

Your healthcare professionals can offer counseling and other support services. But before they do, they need to know if you have other medical and mental health problems. They will test you for these conditions before you leave the hospital and at your follow-up visits to make sure you get the treatment you need. They will continue to recommend support services that allow you and your baby to receive the high-quality healthcare that you need.

***Remember:** The longer you follow your OUD treatment plan, the better your chances are of staying in recovery and strong for your baby. Counseling and support services are important to keep you and your baby safe and healthy at home.*

Next Appointment

Date: _____ Time: _____

Location: _____

Do you have questions for your healthcare professionals?
If so, write them down and take them to your next visit.

[illegible]

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Treating Babies Who Were Exposed to Opioids Before Birth.

SUPPORT FOR A NEW BEGINNING

Introduction.

Many pregnant women with an opioid use disorder (OUD) worry about harmful effects of opioids to the fetus. Neonatal Abstinence Syndrome (NAS) is a group of withdrawal signs that may occur in a newborn who has been exposed to opioids and other substances. NAS signs may include high pitched and excessive crying, seizures, feeding difficulties and poor sleeping. NAS is a treatable condition.

The actions you take or don't take play a vital role in your baby's well-being. Below are some important things to know about what to expect if your baby needs special care after birth, as well as, the Do's and Don'ts for understanding and responding to your baby's needs.

Things to Know.

- A baby born to a mother who used opioids or took OUD medicine during pregnancy is typically observed in the hospital by a medical provider for four to seven days for any physical signs of NAS. A care plan is created for your baby right away if signs of NAS are noted.
- Some babies with NAS may need medicines such as liquid oral morphine or liquid oral methadone in addition to non medicine care supports.
- Other parts of treatment in hospitals include rooming in and putting the baby's crib near your bed. You can also give this type of care to your baby through skin-to-skin contact, gentle handling, swaddling, using pacifiers, breastfeeding and spending quiet time together.
- Your baby will be able to leave the hospital when he/she is successfully feeding and has been monitored for at least 24 hours after no longer needing medicine (if it is used). Some hospitals may also provide medicine for your baby in an outpatient clinic after he/she has been discharged from the hospital.
- Breastfeeding has many benefits for your baby. Breastfeeding can decrease signs of NAS and reduce your baby's need for medicine and hospitalization. Sometimes, breastfeeding is not recommended, so talk with your healthcare professionals to find out what's right for you and your baby.

Medicine Dose and NAS.

If you are taking medicine for your OUD, reducing your dose will NOT help your unborn baby, but it might put your baby at risk. Changing or reducing your OUD medicine while pregnant is not a good idea because it can increase your risk for a return to substance use and might increase the chances of having your baby too early or having a miscarriage. The goal for your OUD medicine dose is to minimize withdrawal and to reduce the chances of going back to substance use.

DO

DO gain the skills and knowledge to understand and respond to your baby's needs. Your baby may need extra contact and cuddling to reduce NAS signs.

DO continue breastfeeding as long as possible when recommended.

DO ask for support so you feel prepared and comfortable with breastfeeding.

DON'T

DON'T change your medicine or dose of medicine without talking to your healthcare professionals.

DON'T be afraid to mention any cravings or urges to use opioids to your healthcare professionals and seek the help you need.

What to expect when you meet with healthcare professionals about OUD treatment after birth.

Before you leave the hospital, your healthcare professionals should describe the signs of NAS and provide you with contact information of someone who can help you if you have concerns. They will make sure that you know how to soothe your baby (for example, dimming lights, softly playing white noise, skin-to-skin contact, using a pacifier and swaddling). They will also explain that the safest sleeping and napping position for a baby is on the back and will show you how to place your baby in the Safe to Sleep position (<http://bit.ly/NIHSafeSleep>). This position and having babies sleep in their own space with nothing in the sleep area reduces the risk of sudden infant death syndrome. You should also expect to have follow-up plans that include home visits and early pediatric follow-up visits (within five days of leaving the hospital).

***Remember:** Before leaving the hospital make sure you receive information on caring for your baby if there are special needs, as well as, names and contact information of others who can give you additional support.*

Next Appointment

Date: _____ Time: _____

Location: _____

Do you have questions for your healthcare professionals?
If so, write them down and take them to your next visit.

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Opioid Use Disorder and Pregnancy.

TAKING HELPFUL STEPS FOR A HEALTHY PREGNANCY

Introduction.

If you have an opioid use disorder (OUD) and are pregnant, you can take helpful steps now to ensure you have a healthy pregnancy and a healthy baby. During pregnancy, OUD should be treated with medicines, counseling and recovery support. Good prenatal care is also very important. Ongoing contact between the healthcare professionals treating your OUD and those supporting your pregnancy is very important.

The actions you take or don't take play a vital role during your pregnancy. Below are some important things to know, about OUD and pregnancy, as well as the Do's and Don'ts for making sure you have a healthy pregnancy and a healthy baby.

Things to Know.

- OUD is a treatable illness like diabetes or high blood pressure.
- You should not try to stop opioid use on your own. Suddenly stopping the use of opioids can lead to withdrawal for you and your baby. You may be more likely to start using drugs again and even experience overdoses.
- For pregnant women, OUD is best treated with the medicines called methadone or buprenorphine along with counseling and recovery support services. Both of these medicines stop and prevent withdrawal and reduce opioid cravings, allowing you to focus on your recovery and caring for your baby.
- Tobacco, alcohol and benzodiazepines may harm your baby, so make sure your treatment includes steps to stop using these substances.
- Depression and anxiety are common in women with OUD, and new mothers may also experience depression and anxiety after giving birth. Your healthcare professionals should check for these conditions regularly and, if you have them, help you get treatment.
- Mothers with OUD are at risk for hepatitis and HIV. Your healthcare professionals should do regular lab tests to make sure you are not infected and, if you are infected, provide treatment.
- Babies exposed to opioids and other substances before birth may develop Neonatal Abstinence Syndrome (NAS) after birth. NAS is a group of withdrawal signs. Babies need to be watched for NAS in the hospital and may need treatment for a little while to help them sleep and eat.

About OUD.

People with OUD typically feel a strong craving for opioids and find it hard to cut back or stop using them. Overtime, many people build up a tolerance to opioids and need larger amounts. They also spend more time looking for and using opioids and less time on every day tasks and relationships. Those who suddenly reduce or stop opioid use may suffer withdrawal symptoms such as nausea or vomiting, muscle aches, diarrhea, fever and trouble sleeping.

If you are concerned about your opioid use or have any of these symptoms, please check with your healthcare professionals about treatment or tapering or find a provider at www.samhsa.gov/find-help.

DO

DO talk with your healthcare professionals about the right treatment plan for you.

DO begin good prenatal care and continue it throughout your pregnancy. These two websites give helpful information on planning for your pregnancy: <http://bit.ly/ACOGprenatal> and <http://bit.ly/CDCprenatal>.

DO stop tobacco and alcohol use.
Call your state's Tobacco Quit Line at 1.800.QUIT.NOW (1.800.784.8669).

DO talk to your healthcare professionals before starting or stopping any medicines.
Do get tested for Hepatitis B and C and for HIV.

DO ask your healthcare professionals to talk to each other on a regular basis.

DON'T

DON'T hide your substance use or pregnancy from healthcare professionals.

DON'T attempt to stop using opioids or other substances on your own.

DON'T let fear or feeling embarrassed keep you from getting the care and help you need.

What to expect when you meet with healthcare professionals about OUD treatment and your pregnancy.

The healthcare professionals who are treating your OUD and providing your prenatal care need a complete picture of your overall health. Together, they will make sure you are tested for Hepatitis B and C and for HIV. They will ask you about any symptoms of depression or other feelings. You should be ready to answer questions about all substances you have used. They need this information to plan the best possible treatment for you and to help you prepare for your baby. These issues may be hard to talk about, but do the best you can to answer their questions completely and honestly. Expect them to treat you with respect and to answer any questions you may have.

***Remember:** Pregnancy is a time for you to feel engaged and supported. Work with your healthcare professionals to gain a better understanding of what you need for a healthy future for you and your baby.*

Next Appointment

Date: _____ Time: _____

Location: _____

Do you have questions for your healthcare professionals?
If so, write them down and take them to your next visit.

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Treating Opioid Use Disorder During Pregnancy.

GETTING THE HELP AND SUPPORT YOU NEED FROM YOUR HEALTHCARE PROFESSIONALS.

Introduction.

Opioid Use Disorder (OUD) is a treatable disease. When OUD is managed with medicines and counseling, you can have a healthy pregnancy and a healthy baby. However, during pregnancy, adjustments to your OUD treatment plan and medicines may be needed.

The actions you take or don't take play a vital role during your pregnancy. Below are some important things to know about OUD treatment during pregnancy, as well as, the Do's and Don'ts for making sure you receive the best treatment possible.

Things to Know.

- Methadone and buprenorphine are the safest medicines to manage OUD during your pregnancy. Both of these medicines stop and prevent withdrawal and reduce opioid cravings, allowing you to focus on your recovery and caring for your baby.
- If you have used opioids, methadone and buprenorphine medicines can help you stop.
- Many pregnant women with OUD worry about Neonatal Abstinence Syndrome (NAS), a group of withdrawal signs that may occur in babies exposed to opioids and other substances before birth. NAS can be diagnosed and treated.
- You may need medicine other than those for OUD to treat pain during or after delivery. Other options, such as an epidural and/or a short-acting opioid, can be used to keep you comfortable.
- All hospitals must report to state child welfare agencies when a mother who is using substances gives birth. This report is used to make sure that a safe care plan is in place to deal with both your and your baby's well-being. It is not used to remove your baby from your care. Participating in OUD treatment before and after the birth of your baby shows your commitment to providing a safe, nurturing environment for your baby.

Treatment vs. Withdrawal.

Some pregnant women with OUD consider completely withdrawing from using opioids, but seeking treatment is always the most helpful course of action. Withdrawal may make you more likely to start using drugs again and even experience overdoses.

If you are not currently in treatment, talk with your healthcare professionals about treatment medicines and behavioral counseling. If you need to find a provider, visit www.samhsa.gov/find-help.

DO

DO ask about the risks and benefits of taking one of the medicines for OUD during pregnancy.

DO talk to your healthcare professionals about your OUD treatment medicine dose if you are experiencing cravings or withdrawal symptoms.

DO ask your healthcare professionals about counseling and recovery support services.

DO make sure your treatment plan includes steps to treat other medical or behavioral health problems such as depression or anxiety.

DO request that your medical chart includes several ways to address your pain during and right after delivery.

DO ask your healthcare professionals to help you make and keep follow-up visits and to talk to each other on a regular basis.

DON'T

DON'T consider changing your OUD medicine unless you are taking naltrexone, which has not been studied in pregnancy. Changing your OUD medicine may increase your risk of returning to substance use.

DON'T use alcohol or any medicines that might make you sleepy, especially benzodiazepines when taking OUD medicines.

DON'T let your OUD go untreated because you want to prevent your baby from experiencing NAS. Treatment medicines can be used safely during pregnancy and dosing changes will not change the risk or severity of NAS for your baby.

What to expect when you meet with healthcare professionals about OUD treatment and your pregnancy.

Creating a treatment plan requires your healthcare professionals to talk to you about the risks and benefits of different medicines and then together select the one that's best for you. You and your healthcare professionals will also discuss other medical conditions or behavioral health problems that could affect your treatment. Your healthcare professionals will help you decide how best to involve your family and friends in your recovery. They can also suggest support groups to join and other services that can help you throughout your recovery.

***Remember:** The benefits of taking methadone or buprenorphine during pregnancy far outweigh the risks of not treating your OUD. You and your healthcare professionals can work together to adjust your treatment plan to achieve success.*

Next Appointment

Date: _____ Time: _____

Location: _____

Do you have questions for your healthcare professionals?
If so, write them down and take them to your next visit.

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Childbirth, Breastfeeding and Infant Care

METHADONE AND BUPRENORPHINE

Are you pregnant, taking methadone or buprenorphine, and want to know how this may affect your delivery, ability to breastfeed or your newborn?

Or are you a pregnant woman using heroin or prescription opioids and considering treatment with methadone or buprenorphine?

How Should I Prepare for Delivery?

- Choosing a doctor and hospital with experience in methadone and buprenorphine during labor and delivery can be helpful.
- Select a doctor for your baby (a pediatrician or family physician) and meet before delivery to talk about the care of your baby.
- Find out whether you can tour the nursery before your baby is born to learn about how the nursery cares for opioid exposed infants.

What About Pain Relief During and After Delivery?

- Your usual daily methadone or buprenorphine dose will not treat pain.
- Discuss pain control for childbirth and after delivery with your physician during prenatal care.
- Meet with the anesthesia doctor to discuss your labor and delivery pain. This meeting can happen before labor or early in labor.
- If you are having a planned cesarean delivery or have one after labor, discuss postoperative pain.
- The doctors on Labor and Delivery MUST know that you are taking methadone or buprenorphine so that you are not given labor pain medications such as Stadol and Nubain which can cause withdrawal in women taking methadone or buprenorphine.

How Does Opioid Withdrawal Affect the Baby After Delivery?

- After delivery, the baby no longer receives nutrients and medications such as buprenorphine and methadone from the mother's bloodstream. Your baby may develop withdrawal – called Neonatal Abstinence Syndrome (NAS).
- Not all babies born to moms on methadone or buprenorphine develop NAS.
- Each baby shows withdrawal differently. The following are some of the most common signs in opioid exposed babies:

- | | | |
|------------------------|------------------|----------------------|
| - Tremors or shakes | - Crying | - Frequent yawning |
| - Poor feeding/sucking | - Sleep problems | - Stuffy nose |
| - Fever | - Sneezing | - Tight muscles |
| - Vomiting | - Diarrhea | - Loose stool (poop) |

What About Child Protective Services?

- Many babies and mothers get tested for drugs and alcohol at delivery – this might include methadone and buprenorphine
- Having a positive drug test, even if it's for prescribed medications, may mean that social workers or a child protection agency will want to talk to you and your family.
- A child services worker may come to your home to see how safe the environment is for your baby.
- Please talk to your doctor and other health care providers about the child protection laws in your state.
- These signs may happen from birth to seven days after delivery and can last days, weeks or months.
- Your baby may need medication to treat these symptoms and make the baby feel better. The baby's dose will then be decreased over time until the symptoms have stopped.
- Your baby may be watched for four or five days in the hospital to see if medication will be needed.
- If a baby has NAS, it does not mean that he or she will have long-term problems

Can I Breastfeed if I Am Taking Buprenorphine or Methadone?

- Breastfeeding is usually encouraged for women who are taking methadone or buprenorphine, except in some cases.
- Breastfeeding is not safe for women with HIV, taking certain medicines or who are actively using street drugs.
- Only very small amounts of methadone and buprenorphine get into the baby's blood and may help lessen the symptoms of NAS.

How Will Having a Newborn Affect My Recovery?

- The weeks and months after the baby is born can be a stressful time for women in recovery. Be sure to continue counseling and use parenting support programs.
- Do not make a decision to stop your opioid medication too quickly or too soon because this increases the risk of relapse.
- It is important to discuss decisions about your medication with your doctors and your counselors. For further information please see brochure Pregnancy and Methadone and Buprenorphine.



Pregnancy

METHADONE AND BUPRENORPHINE

Some women are surprised to learn they got pregnant while using heroin, Oxycontin, Percocet or other pain medications that can be misused (known as opioid drugs). You, along with family and friends, may worry about your drug use and if it could affect your baby.

Some women may want to “detox” as a way to stop using heroin or pain medicines. Unfortunately, studies have shown that 8 out of 10 women return to drug use within a month after detox. Therefore, most doctors treat opioid misuse in pregnant women with either methadone or buprenorphine. These are long-acting opioid medications that are associated with improved outcomes in pregnancy.

How Safe Is It to Take Methadone or Buprenorphine (Subutex®) During Pregnancy?

- In the right doses, both methadone and buprenorphine stop withdrawal, reduce craving and block effects of other opioids. Treatment with either methadone or buprenorphine makes it more likely that the baby will grow normally and not come too early. Based on many years of research studies, neither medicine has been associated with birth defects.
- Babies born to women who are addicted to heroin or prescription opioids can have temporary withdrawal or abstinence symptoms in the baby (Neonatal Abstinence Syndrome or NAS). These withdrawal symptoms (NAS) can also occur in babies whose mothers take methadone or buprenorphine.

Is Methadone or Buprenorphine a Better Medication for Me in Pregnancy?

- A pregnant woman and her doctor should discuss both methadone and buprenorphine. The choice may be limited by which medication is available in your community.
- If a woman is already stable on methadone or buprenorphine and she becomes pregnant, doctors usually advise her to stay on the same medication.

How Can I Get Started on Methadone or Buprenorphine?

- Depending where you live, there may be a special program that offers care to pregnant women who need methadone or buprenorphine. These programs can offer prenatal care and substance use counseling along with your medication.
- Methadone may only be given out by specialized clinics while buprenorphine may also be available from your primary care physician or obstetrician if they have received special training.
- Some women will prefer or benefit from starting these medications while in a residential (inpatient) treatment facility.
- Talk with your doctor about the benefits versus the risks of medication treatment along with the risks of not taking medication treatment.

What is the Best Dose of Methadone or Buprenorphine During and After Pregnancy?

There is no “best” dose of either medication in pregnancy. Every woman should take the dose of methadone or buprenorphine that is right for her.

- The “right” dose will prevent withdrawal symptoms without making you too tired.
- The “right” dose depends on how your body processes the medications.

In pregnancy, you process these medications more quickly, especially in the last several months and this affects what dose you need.

The dose of methadone usually needs to increase with pregnancy – especially in the third trimester and you may need to take methadone more than once a day.

There is less known about buprenorphine dose changes in pregnancy, but increases may be necessary.

The dose does not seem to determine how much NAS a baby will have.

After delivery, the methadone or buprenorphine dose may remain the same or may decrease as your body returns to its non-pregnant state. This can take up to a few months after delivery.

- Your dose should be reduced if it begins to cause sedation. Be sure to discuss whether you are feeling too sleepy with your doctors, nurses and counselors.

For further information please see the brochure Childbirth, Breastfeeding and Infant Care – Methadone and Buprenorphine.

Appendix 3

Local Resources

Network 180: 616.336.3909

Crisis services, psychiatric services, recovery management, target case management.

Mel Trotter Ministries: 616.454.8249

Helps with housing needs.

Degage Ministries: 616.454.1661

Emergency housing for women.

Dwelling Place: 616.454.0928

Low income housing resources.

United Way 211 Program: 211

Basic needs (including food, shelter and clothing).

Salvation Army: 616.454.1459

Detox treatment for substance use disorder, emergency housing, short-term residential stabilization for SUD, long-term residential treatment for SUD.

Our Hope Association: 616.451.2019

Residential substance use services for women.

Family Outreach Center: 616.247.3815

Outpatient mental health, SUD and co-occurring disorder, family engagement program, recovery management.

Interact: 616.259.7900

Assertive community treatment.

Hope Network: 616.454.4777

Targeted case management.

Arbor Circle: 616.459.7215

Outpatient mental health, SUD and co-occurring, family engagement, recovery management, women's case management, specialty pregnancy assistance and SUD at Kent County Jail.

Cherry Health: 616.965.8200

Outpatient mental health, MOUD, target case management, primary medical care, vision and dental care.

Pine Rest: 616.455.5000

Inpatient psychiatric hospitalization, partial psych hospitalization, short-term co-occurring hospitalization, residential SUD treatment, targeted case management, outpatient mental health, SUD and co-occurring, street-reach program.

Forest View Psychiatric Hospital: 616.942.9610

Inpatient psychiatric hospitalization and partial hospitalization.

Center for Integrative Medicine: 616.391.6120

SUD treatment, co-occurring, and primary care.

Recovery Allies of West Michigan: 616.734.3173

SUD recovery, advocates, trainings.

Appendix 4

Patient Resources

ASAM Patient Resources

Opioid Addiction Treatment: A Guide for Patients, Families and Friends.

This patient guide includes information on assessment.

Visit: <https://www.asam.org/resources/patient-resources>

Michigan Department of Health & Human Services Treatment Resources

Helpful information if you or someone you know may have a substance use disorder.

Visit: <http://www.Michigan.gov/opioids>

MIRECOVERY

A website with treatment and recovery support for substance use disorders in West Michigan.

Visit: <http://mirecovery.org/info>

Michigan Narcotics Anonymous Hotline

800.230.4085

Visit: <http://www.michigan-na.org>

The Red Project - Clean Works

616.456.9063

This organization offers free, unused needles, syringes and other supplies to those who need them. The Red Project also provides free testing for HIV and hepatitis C, as well as products for overdose prevention (naloxone) and sexual health.

Visit: <http://www.redproject.org>

Department of Health and Human Services

Treatment for Opioid Disorder and Addiction. How to Find Opioid Treatment Programs?

Visit: <https://www.hhs.gov/opioids/treatment/index.html>

Resources - Advocates for Opioid Recovery

AOR Online Course on Opioid Recovery.

Recognizing and Recovering from Opioid Use Disorder: Keys for Success for Patients and Families.

Visit: <https://www.opioidrecovery.org/resources/>

Appendix 5

Provider Resources

<https://www.asam.org/education/>

<https://www.hhs.gov/opioids/prevention/safe-opioid-prescribing/>

<https://www.ncbi.nlm.nih.gov/pmc/articles>

<https://pcssnow.org/>

<https://www.cdc.gov/drugoverdose/index.html>

<https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf>

<https://www.aha.org/bibliographylink-page/2018-09-28-treatment-options-opioid-use-disorders>

<https://medicine.umich.edu/dept/psychiatry/programs/michigan-opioid-collaborative-moc>

Appendix 6

Pre-Charting Tool

In _____ Room _____

Ultrasound _____ MOUD _____ PNV _____

BP _____ Weight _____ Weeks of Gestation _____

Every Visit: ☐ Feels Safe ☐ Has Script for Naloxone

In Counseling with: _____ Last Appt: _____ ☐ Smoking

First Visit

☐ Prenatal Labs Completed ☐ Physical Completed ☐ Welcome Pack

☐ Sign Consents ☐ Complete the PHQ 9 ☐ Suggest TB Screen

28 Week Labs

☐ Birth Plan Reviewed ☐ Pain Management ☐ Referral to NICU ☐ Childbirth ED

☐ Birth Control Plan/Sign Consent for TL ☐ NAS Handouts Given ☐ Has Provider for Baby

☐ Labs Ordered ☐ Rhogam ☐ Antibody Screen ☐ Tdap

36 Weeks

☐ Discuss Breastfeeding Plans ☐ GBS ☐ Discuss Length of Stay for Baby

☐ Repeat HIV, Syphilis and GC/Chlamydia

Postpartum

Two Weeks: ☐ Discuss PP Depression ☐ Edinburgh

Six Weeks: ☐ Discuss PP Depression ☐ Edinburgh

☐ Transfer care to _____ for MOUD

Rooming Tool

In _____ Room _____

Ultrasound _____ MAT _____ PNV _____

BP _____ Weight _____ Weeks of Gestation _____

Every Visit: ☐ Feels Safe ☐ Has Script for Naloxone☐ In Counseling with: _____ Last Appt: _____ ☐ Smoking**First Visit**☐ Prenatal Labs Completed ☐ Physical Completed ☐ Welcome Pack☐ Sign Consents ☐ Complete the PHQ 9 ☐ Suggest TB Screen**28 Week Labs**☐ Birth Plan Reviewed ☐ Pain Management ☐ Referral to NICU ☐ Childbirth ED☐ Birth Control Plan/Sign Consent for TL ☐ NAS Handouts Given ☐ Has Provider for Baby☐ Labs Ordered ☐ Rhogam ☐ Antibody Screen ☐ Tdap**36 Weeks**☐ Discuss Breastfeeding Plans ☐ GBS ☐ Discuss Length of Stay for Baby☐ Repeat HIV, Syphilis and GC/Chlamydia**Postpartum**Two Weeks: ☐ Discuss PP Depression ☐ EdinburghSix Weeks: ☐ Discuss PP Depression ☐ Edinburgh☐ Transfer care to _____ for MOUD

Appendix 7

Clinical Opiate Withdrawal Scale (COWS)

Flow-sheet for measuring symptoms over a period of time, during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date: _____

Buprenorphine Induction: _____

Enter scores at time zero, 30 minutes after first dose, two hours after first dose, etc.

Resting Pulse Rate: Record beats per minute. Measured after patient is sitting or lying for one minute. 0 - Pulse rate 80 or below. 1 - Pulse rate 81-100. 2 - Pulse rate 101-120. 4 - Pulse rate greater than 120.				
Sweating: Over past hour not accounted for by room temperature or patient activity. 0 - No report of chills or flushing. 1 - Subjective report of chills or flushing. 2 - Flushed or observable moistness on face. 3 - Beads of sweat on brow or face. 4 - Sweat streaming off face.				
Restlessness: Observation during assessment. 0 - Able to sit still. 1 - Reports difficulty sitting still but is able to do so. 3 - Frequent shifting or extraneous movements of legs/arms. 5 - Unable to sit still for more than a few seconds.				
Pupil Size: 0 - Pupils pinned or normal size for room light. 1 - Pupils possibly larger than normal for room light. 2 - Pupils moderately dilated. 5 - Pupils so dilated that only the rim of the iris is visible.				
Bone or Joint Aches: If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored. 0 - Not present. 1 - Mild diffuse discomfort. 2 - Patient reports severe diffuse aching of joints/ muscles. 4 - Patient is rubbing joints or muscles and is unable to sit still because of discomfort.				

Runny Nose or Tearing: Not accounted for by cold symptoms or allergies. 0 - Not present. 1 - Nasal stuffiness or unusually moist eyes. 2 - Nose running or tearing. 4 - Nose constantly running or tears streaming down.				
GI Upset: Over last hour. 0 - No GI symptoms. 1 - Stomach cramps. 2 - Nausea or loose stool. 3 - Vomiting or diarrhea.				
Tremor: Observation of outstretched hands. 0 - No tremor. 1 - Tremor can be felt, but not observed. 2 - Slight tremor observable. 4 - Gross tremor or muscle twitching.				
Yawning: Observation during assessment. 0 - No yawning. 1 - Yawning once or twice during assessment. 2 - Yawning three or more times during assessment. 4 - Yawning several times/minute.				
Anxiety or Irritability: 0 - None. 1 - Patient reports increasing irritability or anxiousness. 2 - Patient obviously irritable anxious. 4 - Patient so irritable or anxious that participation in the assessment is difficult.				
Gooseflesh Skin: 0 - Skin is smooth. 3 - Piloerections of skin can be felt or hairs standing up on arms. 5 - Prominent piloerections.				
TOTAL SCORES with Observer's Initials				

Score: 5 to 12 = Mild; 13 to 24 = Moderate; 25 to 36 = Moderately Severe; More than 36 = Severe Withdrawal

Appendix 8

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Appendix 9

Phone Triage

Flowchart for GREAT MOMs Patient Calls to RN Triage for Buprenorphine Issues.

